TDH RESPONSE

<u>to</u>

Questions from April 2, 2015

CN1407-027 Implanted Pump Management & CN1411-046 Pentec Health, Inc.

The Mission of the Tennessee Department of Health is to protect, promote, and improve the health and prosperity of people in Tennessee. TDH's responses to questions posed by the Health Service and Development Agency regarding the proposed institution of intrathecal pump maintenance services by a home health agency follow.

- 1. Does the Tennessee Department of Health (TDH) have any way to determine the actual number of intrathecal pumps in Tennessee? For example, is there any type of registry or does the Board of Medical Examiners (BME) keep any type of information?
 - **TDH Response**: TDH is not currently able to determine the number of intrathecal pumps in Tennessee. Neither TDH nor the BME maintains any such registry, and TDH is not aware that any such registry exists in Tennessee.
- 2. Do physicians prescribing intrathecal pumps for pain management have to meet any additional requirements beyond what a typical physician would have to meet? For example, would physicians prescribing this type of care need specialty board certification such as interventional pain management or would their offices be required to be certified as a pain clinic by the Board of Medical Examiners?

TDH Response: The Tennessee Home Health Agency rules and regulations (HHA R&R) do not mandate any such certification. The HHA R&R advise that ongoing educational programs be planned and conducted to develop and improve the skills of personnel.

Insertion of an intrathecal pain pump constitutes interventional pain management under TCA Section 63-6-244 and, as such, a physician engaging in this practice would have to be board certified in one of a few specified areas or meet one of the other qualifications either in statute (TCA Section 63-6-244) or rule (BME Rule 0880-02-.14(14)). Neither TDH nor the BME licenses or credentials for these specified areas. As a result, the BME doesn't have access to information regarding the number of physicians qualified and engaging in this practice. Prescribing the drug to be contained in the pump does not fall under the BME Rules (the usual rules relating to prescribing would apply).

It is not clear that performing the actual refill also constitutes interventional pain management (the definition in TCA 63-6-244(b) is broad, "...performing invasive procedures involving any portion of the spine..."). The insertion of the needle into the catheter structure that has been inserted directly into the spine may qualify as invasive despite the needle not being inserted directly into the spine itself.

3. A. How often would a physician need to see a patient for an assessment before prescribing refills for the pumps? If a physician is required to see the patient each time before prescribing refills, is there any benefit to this home care model?

TDH Response: HHA R&R do not mandate a face-to-face visit with the physician. The HHA R&R state the plan of care is to be reviewed every 62 days, and a written summary of the patient's status is provided to the physician every 62 days.

There is not a requirement in the BME Rules regarding how often the physician would need to see the patient. Opioids cannot be dispensed in greater than a 30-day supply, although that does not mean that practitioners must see the patient every 30 days. There are also BME Rules 0880-02-.14(6)(e) and (7) that require a physician to conduct a physical exam in order to prescribe, particularly for controlled drugs. However, an exception exists in (7)(b) of that rule for established patients.

B. Does TDH believe the need for this type of service is being met in the physician office setting?

TDH Response: TDH does not have direct knowledge or access to data to answer this question, and is not currently aware of any lack of available services in this regard. A patient receiving this service in a physician office setting is not homebound; initially, all patients initially receive the implanted catheter in a physician's office or surgical setting.

C. If a home option became available, would any physicians be expected to stop providing this service in the office?

TDH Response: TDH does not have information or data that permits it to answer this question. TDH and the BME believe that there is value in the physician seeing and examining the patient on a regular basis.

D. Who currently provides the refill in the physician office setting? Does the physician do it or a physician extender or registered nurse? Are there any circumstances when someone less credentialed than an RN could provide the refill (such as an assistant)? If someone other than the physician is providing the refill, is direct oversight required?

TDH Response: Since neither TDH nor the BME licenses physician offices or credentials them to engage in this practice, TDH cannot answer this question. It should be noted that TCA Section 63-7-126 only permits an Advanced Practice Nurse or a Physician's Assistant to perform interventional pain procedures under "direct supervision," which means physically present in the same building at the time of the procedure. However, there has not been a determination regarding whether the refill is an interventional pain procedure itself or is instead a maintenance procedure.

4. Can TDH provide any insight from its resources or those of its stakeholders relative to how reimbursable costs of in-home intrathecal infusion pump services provided by the two applicants might compare to the cost of providing the service to patients in the physician office setting? If so, can the data be provided by the major CPT codes that apply to the service? See p. 140, Pentec application, for codes.

TDH Response: TDH does not have access to data by CPT code usage and is thus unable to answer this question.

5. A. Have TDH's concerns about shipping directly to the applicant's staff nurses been allayed [by information in transcript and from applicants? If not, please confirm the federal or state requirements that prohibit this type of activity.

TDH Response: The Tennessee Board of Pharmacy (BOP) is charged with enforcing federal and state laws in this area. BOP staff have spoken with and received emails from the US Drug Enforcement Agency (DEA) indicating that the delivery model does not meet federal requirements, and even though it may be "overlooked" in some areas of the country, if a license application is received the BOP will refer the matter to the Nashville office of DEA for consideration and react accordingly.

B. Please identify the controlling state and federal requirements regarding controlled substances.

TDH Response: US Code of Federal Regulations, Title 21, Chapter II, Part 1306. TCA Sections 39-17-402 (26), 53-10-104, 53-10-105, 53-10-108, 53-11-301, 53-11-302, 53-11-308, 53-11-401, 63-10-204 (12), 63-10-204 (13).

C. Please provide more details regarding state and federal compounding pharmacy requirements. Given the recent concerns regarding the fungal meningitis outbreak due to problems in out-of-state compounding pharmacies, how does the department regulate those pharmacies going forward? Are there any special concerns related to the compounding of the drugs that will be utilized in the implanted pumps? Will TDH approve dispensing by a pharmacy to the applicant home health agency as originally described (direct to staff nurse for transport to home health patient)?

TDH Response: Compounding for intrathecal use via implanted pumps has one of the highest pharmaceutical delivery risk levels, and also contains some of the strongest pain medications available. The BOP aggressively inspects sterile compounders located inside Tennessee at least annually and has a process to allow immediate action should the pharmacy not meet the guidelines of the BOP's pharmacist investigators. TCA Section 63-10-216 requires out-of-state compounders to be inspected by their home state's agency within 12 months of the issue or renewal of their Tennessee BOP License. TDH and the BOP have confidence in the BOP's inspection process for in-state compounders, but do not have the same level of comfort with the inspection of out-of-state compounders by their home state agencies. The TDH response to Question No. 5 A, above, addresses the last question in 5 C, immediately above.

D. Are there drug safety concerns regarding the drugs being shipped to the nurse versus being shipped to the home? Is the risk of the drugs being tainted or damaged in some way greater in one scenario than the other? Are there time and/or temperature concerns?

TDH Response: Storage of controlled substances subjects the holder of drugs to risk of burglary, robbery, and other crimes. Pharmacies with major security and advanced alarms are frequently burglarized and robbed; TDH questions whether a nurse's home could be adequately protected so as to make controlled substance storage safe or secure. TDH additionally wonders how a nurse would be able to defend him/herself against patient allegations of theft, tampering, adulteration, or other damage. Regarding temperatures, drugs can be packaged and shipped properly to withstand temperature fluctuations for a short time, but timely retrieval and proper storage of drugs is necessary.

E. How can the receipt and proper use of opiates be monitored and regulated if these applications are approved? How could opiate abuse (illegal use and distribution) by home health personnel be avoided?

TDH Response: The HHA would be expected to have policies and procedures in place to address these concerns. The HHA R&R direct a licensed HHA to have an appropriate and effective pain management program to be in place. TDH has no other way to monitor and regulate the receipt and proper use of opiates, and thus believes that there is currently no way to guarantee that opiate abuse would not occur.

6. A. Could TDH survey states where this process is more common to determine what they have learned about intrathecal pump infusion by a home care agency – for example, the pros and cons of this type of service in the home setting. It would be helpful to learn about the regulatory compliance for these applicants in other states (all states bordering Tennessee except Arkansas; New York and Illinois).

TDH Response: The following states were reviewed: North Carolina, Virginia, Georgia, Alabama, Mississippi, Missouri, New York, and Illinois. North Carolina and Virginia include intrathecal pumps within the definition of infusion therapy. Each state has specific regulations guiding infusion and intrathecal pump services provided by a home care agency. Alabama code does not appear to address home health agencies. The remaining states do not have rules or regulations in law regarding intrathecal pump services provided by home care agencies. However, these states have rules and regulations in place for home health agencies that may be applicable to intrathecal pump infusion provided by a home care agency.

a. Kentucky: http://chfs.ky.gov/os/oig/dhcfs.htm

It isn't clear how Kentucky categorizes services in its home health facilities for regulation; however, it appears unlikely that it singles out in-home intrathecal pumps from other home health regulation.

b. Virginia: http://www.vdh.virginia.gov/OLC/laws/

Virginia regulates intrathecal services with other home health agency infusion therapy services. Please see 12VAC5-381-350, Pharmacy Services, for specific information at the above link.

c. North Carolina: http://www.ncdhhs.gov/dhsr/testrules.htm

North Carolina regulates intrathecal services with other home health agency infusion therapy services. Please see 10a NCAC 13j .1108 INFUSION NURSING SERVICES at the above link for specific information.

d. Georgia: https://dch.georgia.gov/hfr-laws-regulations

Georgia does not appear to regulate intrathecal services separately from other home health agency services.

e. Alabama: http://www.adph.org/HEALTHCAREFACILITIES/Default.asp?id=5344

Alabama does not have regulations for home health agencies.

f. Mississippi: http://msdh.ms.gov/msdhsite/static/30,0,83,60.html

Mississippi does not appear to regulate intrathecal services separately from other home health agency services.

g. Missouri: http://health.mo.gov/safety/homecare/

Missouri does not appear to regulate intrathecal services separately from other home health agency services.

h. New York: https://www.health.ny.gov/facilities/

New York does not appear to regulate intrathecal services separately from other home health agency services.

Illinois: http://www.idph.state.il.us/about/ohcr.htm

Illinois does not appear to regulate intrathecal services separately from other home health agency services.

B. Is compliance information desired from these states on this particular type of service provider?

TDH response: TDH believes this information might help inform the HSDA about specific applicants.

7. The patient to nurse ratio of 40 to 1 seems unrealistic especially since both applicants sought to cover a large geographic area such as Tennessee. Does TDH believe this is a realistic staffing ratio given the nature of the services being proposed?

TDH Response: A concern clearly could arise in the instance of a patient emergency situation and the ability of the nurse to make it to the patient's home within a reasonable amount of time.

8. If all the concerns regarding controlled substances were resolved, is this specialty type singular home health service a better care model than one where an existing full-service agency would contract with a specialty provider? In the former, the specialty provider would notify the patient's physician of any additional problems and assist in coordinating follow-up care under physician's orders with another separately licensed home health agency, as appropriate. In the

latter, a full service agency would contract with the specialty provider to provide the specialized services while the full-service agency would oversee all the care provided.

TDH Response: A plus to the proposed specialty model could be having specialized staff members concentrate on one area of service, contributing to better patient outcomes.

9. Should this application be approved?

TDH Response: TDH believes the response to this question is the HSDA's responsibility; however, in particular, the responses to Question No. 5 show TDH's level of concern regarding the provision of this service.



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

DATE:

June 10, 2015

TO:

HSDA Members

FROM:

Melanie M. Hill, Executive Director

SUBJECT:

CN1407-027, Implanted Pump Management, LLC & CN1411-046, Pentec Health, Inc.

Response to Agency Questions

On March 25, 2015, the HSDA heard the referenced applications and deferred both so additional information could be obtained. Questions were submitted to both applicants and to the Department of Health. The information below includes a summary of the applicant's responses. Included for you review is a transcript of the March 25, 2015 Agency meeting and each applicant's response to the April 2, 2015 questions. The Tennessee Department of Health's response will be forwarded once it has been received. Please refer to your copy of the original application (which can also be accessed from the agency's website at this link: http://tennessee.gov/hsda/committee packets/Mar15 packet.html). Pentec has also submitted a response, dated 6/4/15, to IPM's response to Question 13. It is attached directly behind the 5/22/15 Pentec responses.

The table below provides a brief summary of the two projects.

Implanted Pump Management, CN1407-027, and Pentec, CN1411-046

Item	IPM	Pentec
Project Cost	\$13,038	\$142,028 (100 k for contingency)
Skilled Nursing Services	Refills for Intrathecal pumps only	Refills – Intrathecal Pumps and
-focuses on medication admin.		Meds for Ig-G replacement
under physician orders		therapy (willing to exclude this
		service) Sup 2 -pgs. 241,251,252
Target Patient Types	Chronic pain, CA pain, CP, MS	Same as IPM
	(YR 1=108 pain, 11 CP, 2 MS)	YR 1 = 17 in East; 14 in Middle
	Sup 2 –p221-224	and 8 in West at year end
Est # IP Pumps in TN in CY2014	300 IP pumps	1,976 IP pumps
Projected # IP Patients (Year 1)	120 patients	20 IP patients (avg. per month)

Projected # Visits (Year 1)	1,440 visits (12 per patient – 1 visit every 30 days)	120 IP visits (6 per patient- 1 visit every 60 days) Note: Applicant estimates 1,020 IgG patients in TN as of 12/2015
Compounding Rx Support	By contract- Intrathecal Compounding Specialists (LA) and Basic Home Infusion (NJ) TN licensed since 2008 and 2009	Pentec owned/ closed compounding pharmacy at corporate office in Boothwyn, PA. TN licensed since 2004
Dispensing Note: both proposals involve compounding Rx prep, packaging & shipping by pharmacies who hold existing out of state TN pharmacy licenses	Contract pharmacies (2 identified by applicant) ship to RN or patient. Note: at March HSDA meeting IPM owner (Putrino) stated they would change model to ship from compounding pharmacy to patient and would use an instate licensed compounding pharmacy to comply with TDH requirements Sup 1-p113;Sup3-p269 Transcript, p.16	Pentec's wholly owned pharmacy ships to RN. Note: at March HSDA meeting, Pentec Rep (Wynd) stated that Pentec's IP med shipping model of its licensed HHAs in 32 states complies with state and federal (DEA) requirements. Wynd stated Pentec is confident in its delivery system and most likely would not entertain changing the model for the proposed TN service. Sup1-p147,165; Sup2-p249 Transcript, page 97
Payment Source	Commercial, Private	Commercial, Private (includes partial pay) Sup 2, p245 20 of 39 commercial by year end See app-p 81 and Sup2-p233 for plans/charges
Medicare-TennCare – CMS covers Rx & DME only and not skilled nursing home health visits	IPM has no charity policy for these recipients	Will cover recipients as partial pay or charity.
Gross Operating Revenue Average Gross Charge Gross Operating Margin Operations History	\$288k-\$576k \$200 per visit 47% of gross rev BHI has pharmacy license in 14 states (per Putrino at March meeting) IPM has HHA licensure pending in FL, NJ, UT -No IP patients served yet	\$305k-\$854k \$2,517 per visit 14% of gross rev Pharmacy licensed in 50 states & DC HHA health licensure in 34 states (sup 2, p255) 1,303 IP home patients in 2011 2,177 IP home patients in 2013 (At March HSDA meeting, Pentec rep stated approx. 2,800 IP patients were served in 2014)

Support Letters	2 patients, 3 pump vendors, 2	I physician (5 or more initially identified
	physicians	in application –p81)
Staffing	1 RN to 40/50 patients (start	1 RN to 40 patients (start with
Both provide 24 hour call center	with 2 FTE)	2.5 FTE)
support, secure web portals for	180 mile radius	Mandatory nurse training-ANC
patients and physicians, etc.	Mandatory nurse training	certified. Sup2-p254
Service Area (statewide)	95 counties	92 counties
Est 2.2 million TN residents with	No existing HHA actively serving	
chronic pain, 2,000 with CP,	IP patients	
7,200 with MS		
Home Health Need formula	81,600 surplus statewide	80,773 surplus in 92 counties

The following questions were asked of each applicant. A brief summary of their responses follows.

 Based on the information provided by the Tennessee Department of Health, it appears implantable intrathecal pumps may not be safe. Please provide expert opinion on the safety and efficacy of the pumps.

<u>Pentec -</u> provided opinion from Dr. Stanley Fisher, M.D, St Luke's Neuroscience Institute, Kansas City (bio was included). His comments address the inherent risk of intrathecal pumps (IP), the prevalence of use since FDA approval in 1999 (approximately 80,000 pumps nationwide in 2014), and Pentec's safety protocols for IP medication refills (only in-home service to be provided).

<u>IPM</u> – provided opinion from two sources (a) David Caraway, MD, PhD, Medical Director Center for Pain Relief, St. Mary's Regional Medical Center, Huntington, WV, and (b) overview in clinical/patient literature published by Medtronic (pump manufacturer) dated 4/1/08. Dr. Caraway's letter highlights advantages of IP refills over oral meds for target patient populations (MS, CP, Pain); need for continued oversight by physicians (he recently transferred IP refill management of 200 plus patients to a home health agency. This pain management physician has published reviews of numerous medical studies with colleagues. The Literature Review (Intrathecal Drug Delivery for Chronic Pain Literature Review) defines the use of IPs, its benefits in terms of effectiveness as treatment of last resort by physicians and risks such as complications from wound infections.

2. Describe in detail the safety of refilling the pumps in the home versus a physician office. Who refills the pump in the physician office setting.....is it the physician or a nurse or someone else? If someone other than the physician, detail the oversight provided by the physician.

Note: the responses for this item point out differences between settings. For example, various staff in physician office can be assigned IP refills additional other patient responsibilities (RNs, LPN or med assistants), or physicians may decide to personally administer the refill. Pentec notes that medical pump manufacturers may provide most of the ongoing education support. The key point both make is that the home health agency is inherently the safer setting since they focus on in-home IP refill management as a sole service and RN staff must complete specialized training.

3. Address the risks associated with accessing the spinal port in the home. Provide any statistics for incidents, adverse events, or reported complications over the past 3 years and the outcomes. Both applicants have noted having a national presence in the implanted pump market so additional clarification regarding safety issues is needed.

Note: The responses point out the risks are the same in physician offices with some exceptions such as better infection control in the home setting. Two key risks are described (subcutaneous infection & pump programming errors. Pentec lists safeguards in place to minimize these). Pentec identifies several statistics from its records. For example, it had two patient emergencies during the 3 year period ending April 2015 (partial subcutaneous administration errors) on approximately 28,855 total IP refills during the period (Note: based on information provided in the application and the March 2015 Agency meeting, HSDA staff estimates that approximately 5,800 – 6,000 patients may have been served during this 28 month period)

IPM did not provide the same level of detail, but notes the home health agency error rate is less than 2% of total pump complications.

4. Describe when the procedure is clinically contraindicated (when a refill will not be performed).

Note: both applicants gave specific examples. IPM includes description of notification to physicians. Examples of circumstances include inability to access pump reservoir, infection, fluid accumulation, an inverted pump, or concerns with catheter tubing.

Describe in detail how the medications will be protected from theft, misuse, and/or abuse from the time the nurse receives the medication until it is delivered to the home.

Note: both applicants addressed their medication delivery systems during initial review of the applications. Their responses to this question are consistent with those responses. During the March Agency meeting, IPM agreed to change its shipping protocol to send implanted pump meds direct to patient homes per TDH requirements (page 87 of transcript) and to contract with a Tennessee licensed compounding pharmacy whose preparation and distribution facility is physically located in Tennessee (page 16 of transcript). Pentec notes that it shipped 6,581 implanted pump med packages in 2014. Of these, there were only two circumstances where inaccuracies were noted. Key features used to help control the process include custom designed scheduling systems, cross check of shipping documents by pharmacists and staff nurses, inventory by staff nurse on delivery, and the use of lock boxes and tamper proof caps. Additional detail - Pentec included copies of three existing corporate policies & procedures used by its specialty infusion and pharmacy divisions.

How will the proper use of opiates be monitored and regulated?

In addition to internal protocols by the applicants, IPM notes that Tennessee regulators could track proper opiate use through existing controlled substance tracking systems and MD monitoring.

Have there ever been incidents of opiate abuse by employees of your company in any of the other states in which you operate? If so, please describe in detail how those were handled.

Note: both applicants responded to the question. IPM reported no violations or issues. Pentec identified one instance of diversion by a nurse employee in 2009 and described what was done to report the incident and develop & implement a plan of correction. Since the incidence in 2009, Pentec notes it has performed 50,000 IP refills in six years with no further diversions noted.

5. Emergency procedures were addressed in the applications, but more detail is requested. What are the emergency procedures if there is an adverse reaction during the refill procedure? After the procedure is complete and the nurse is still in the home? When nursing personnel are not in the home? After the procedure, and nursing personnel have left the home?

Note: the additional detail requested was provided by Pentec (copies of 2 corporate policies and physician responsibilities per patient plan of treatment per state law). Otherwise, both applicants provided descriptions of actions staff nurses and patients should take when or if emergencies occur, including notification to physician, the IPM or Pentec 24 hour on call center and calling 911.

6. The patient to nurse ratio of 40 to 1 seems unrealistic, especially since both applicants sought to cover a large geographic area such as Tennessee. How many nurses would it take to provide adequate coverage in Tennessee, and from where would you hire these skilled nurses?

Note: both applicants addressed this in the application and supplemental responses and have a similar 40 to 1 staffing plan. IPM clarified that it would also staff on the basis of a 180-mile radius from the IPM nurse to the patient. Pentec operates in-home skilled nursing IP refill service in approximately 30 states and has experience with this type of staffing plan. Pentec identified state requirements for home health organizations that may otherwise impact its staffing plan such as service areas limited to a 100 mile radius from applicant's parent office (per Kansas and New Mexico requirements). These restrictions are noted in the state-by state analysis Pentec provided on pages 125–132 for question 11 of the letter.

7. During the March 25, 2015 Agency meeting, Mr. Doug Wynd, Pentec National Sales Director of Specialty Infusion, stated there were approximately 80,000 individuals with implanted intrathecal pumps in the U.S, including 75,000 receiving ongoing care from their physicians and 5,000 receiving care in their homes from licensed home health agency nursing staff under physician orders. Mr. Wynd noted Pentec was serving approximately 2,800 of the 5,000 in the home setting (draft transcript, pages 37 and 53). Due to the wide variation in estimates of implanted pumps in Tennessee (IPM used 300 Medtronic implanted pumps while Pentec estimated approximately 1,730 total pumps) please clarify the difference in the two estimates, and document the basis for the estimates.

Note: both applicants described how their estimates were derived and clarified remarks made at the March 2015 Agency meeting. IPM notes that Medtronics sold 621 implanted pumps to facilities in Tennessee in CY 14-15 (595 of the pumps were implanted). IPM also notes that there are another two pump vendors in Tennessee with the result that the current number of pumps in the state could be at least three times higher. Pentec bases its estimate using a population methodology. Specifically, it

multiples Tennessee's population rate (2.05% of US population) by 80,000 exiting implanted pumps in use in the U.S. to arrive at a minimum of 1,640 implanted pumps in the state, increasing to 1,976 pumps when taking Tennessee's health status ranking into account (source of market data is from HMS Holding Corporation).

Please identify the number and source(s) of patients that are presently being treated in a physician's office in Tennessee. Are any physicians expected to stop providing this service in the office if a home health option becomes available?

Note: both applicants appear to agree that 100% of implanted pump patients are being treated in physician offices. Pentec's experience is that approximately 10% of existing pump patients could be referred for in-home treatment support.

8. Please provide testimony (in person or by letter) from physicians with practices in each Grand Division of Tennessee (East, Middle, and West) who would support this specialty service in the home, including the approximate numbers of patients needing this service. Provide sufficient letters to support the service area requested.

Provide letters of support from patients in each Grand Division of Tennessee not being treated due to not being able to travel to a physician's office as well as from patients who would find this home option more convenient. Provide sufficient letters to support the service area requested.

Note: both applicants provided letters from physician groups and some patients – there are few letters of support as was the case during initial review of the application. One new development is that physician practices have wider geographic service areas with patients from all parts of the state. To help demonstrate this, the applicants used surveys to help identify caseloads of the physician practices. The Pentec response also identified support by Comprehensive Pain Specialists, a physician practice that treats patients through 28 office locations across the state.

9. How often does a physician have to see the patient before these medications can be refilled?

Note: both applicants state that the frequency in most cases is 30 – 60 days. However, they note that frequency will vary as directed by physicians through physician treatment plans that must be updated every 60 days in accordance with state regulations.

10. What is the current estimated cost and payor reimbursement by major CPT codes pertaining to intrathecal implanted pump refill visits in physician offices in TN? How does this compare to your cost and reimbursement?

IPM projects an average gross charge of \$200/visit while Pentec identified \$2,517/visit. Although total gross revenue of both applicants is very close in Year 1 (approximately \$300K), the difference in projected patient visits results in a wide variance in the projected average gross charge. Please identify the key components of your rate structure with related CPT codes used to bill for implanted pump refills in physician offices, home health, and pharmacy settings. Note: For purposes of comparison, it is suggested the key components of the proposed rate structure identified in the Pentec application be used in the response for this question. Specifically, the rate would include the charges by four basic categories - medications, supplies/materials, nursing time

and a per diem that covers allocated corporate support costs, such as IT, billing, etc. (transcript, Pentec presentation, page 54-55).

Note: there is really no new information provided by IPM – it continues to assert that its \$200 rate is for skilled nursing only because it subcontracts for pharmacy services. As a result, the additional detail in the response by Pentec appears to provide further clarification of how its average gross charge was revised to \$2,471 per patient visit during HSDA's completeness review of the application, inclusive of charges for medications, nursing labor, supplies, and a per diem charge. Pentec notes that its rate structure has been reviewed and accepted by the nine payers in Tennessee shown on the table in page 20 of the response. Of interest, Pentec states that HCPS codes apply to infusion therapy pharmacy providers (including home health agencies) in lieu of CPT codes that apply to physicians (HCPS = healthcare common procedure coding system). This was confirmed through HSDA communications in April 2015 with Mr. Bill Noyes, Vice President, National Home Infusion Association (NHIA). Mr. Noyes also provided insight on his association's development of legislation to expand Medicare coverage of infusion therapy for patients in their homes (the legislation was recently introduced in Congress under the Medicare Home Infusion Site of Care Act of 2015). As part of the legislation, a study sponsored by NHIA (The Avalere Report) was used to help identify the potential savings to the Medicare program. The report identified an estimated \$80 million in savings to Medicare over a 10 year period from 2015-2025 if coverage for in-home care were to be added to existing Medicare coverage of infusion therapy services in hospitals, hospital outpatient departments, physician offices, and skilled nursing facilities. The legislation and the report can be found on NHIA's website at http://www.nhia.org

11. Provide comprehensive state regulations for each state in which you operate this type program. How are these agencies regulated by each state, as home health agencies or pharmacies or as some other type entity? Disclose and discuss any sanctions of existing licenses in other states in which you operate this type program and provide evidence that your company is in good standing.

Note: Pentec provided a state-by-state analysis in a table on pages 125-132 of its response. IPM provided a brief description of applicable requirements and a list showing home health and pharmacy licenses by state currently held by IPM and Basic Home Infusion (BHI), a New Jersey Corporation related to the applicant through ownership by Roy Putrino. With respect to home health licensure only, the list shows that IPM has home health licenses in Florida, Utah, and Virginia while BHI holds licenses in Illinois, North Carolina, and Texas.

According to Pentec, it holds licenses classified as a home health agency in 10 states, under different licensure classifications in five states (e.g. home nursing agency, home care agency), and provides in-home implanted pump services in 14 states, where licensure at the entity or agency level is not required.

Have you ever been denied a certificate of need or a license (home health or pharmacy) in any state? If so, please provide documentation such as staff reports, minutes, denial letters, and/or transcripts.

Note: both applicants answered in the negative. IPM noted it received CON approval from Kentucky in November 2014 to provide intrathecal infusion pump home management services as a "mobile health service" in all but 4 counties of the state.

12. Did either applicant consider contracting with existing home health agencies to provide this service? If not, please explain why. In a contractual situation, the services could be provided under an existing agency's license utilizing IPM or Pentec nurses to provide the service. Discuss the pros and cons of this scenario and how reimbursement would differ.

Note: Of the two applicants, only Pentec appears to have seriously considered the advantages and disadvantages of this scenario with highlights of same fully addressed on pages 24-26 of its response. IPM identified major disadvantages associated with subcontracting with an existing licensed agency stemming from patient safety concerns based on the specialized nature and scope of providing a skilled nursing implanted pump management service in the home setting.

13. Should the Agency determine there is a need for this type specialty home health agency, would the applicants be willing to consider approval for only half of the service area requested so that two agencies would cover the state instead of just one? Would the project still be financially feasible if only a portion of the service area were approved?

Note: both applicants are opposed to this scenario. IPM states this is an unsafe option due to Pentec's "ongoing FDA investigation that illustrates unsafe pharmacy conditions" (review of the FDA/DEA website by HSDA staff on 6/1/2015 revealed that Pentec's Boothwyn, PA compounding pharmacy had several citations related to preparation of some renal products used by the company's Renal Division. Please note that Pentec has filed a separate response, dated 6/4/15, to this allegation. This investigation and related actions to correct the situation were addressed in the application and by the Pentec representative at the March 2015 HSDA meeting in Nashville).

Pentec opposes the scenario as a "geographic restriction" that would unnecessarily limit physician referrals of patients who reside in wider geographic areas across Tennessee.

14. The final question is for Implanted Pump Management. In the application and during testimony on March 25, 2015, Mr. Putrino indicated his infusion pharmacy company, Basic Home Infusion, had licensed pharmacies in 14 states and that IPM would be operating home health agencies in three states—Florida, Utah, and New Jersey. Mr. Putrino is quoted on page 16 of the attached transcript as saying "This model has allowed us to grow to a national level via word of mouth, and it is our desire to bring this model to Tennessee" and on page 95 as saying "Let's take this regional contract and make it national." Please explain these comments about going national with only three not yet operational home health agencies. Is IPM or its sister infusion pharmacy company providing direct hands-on skilled nursing services in other states directly to patients via contracts with individual nurses or in some other manner?

Note: Mr. Putrino states that IPM was established with guidance from the Joint Commission to better conform to each state's nursing regulations and to streamline the process. Mr. Putrino also provides some information that may help further appreciate some of the differences between IPM and BHI. A key difference appears to be the scope of BHI coverage in the U.S. based on its licensure as a compounding pharmacy to provide intrathecal therapy in 45 states in accordance with requirements set forth by each state's Board of Pharmacy.

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HSDA TRANSCRIPT

MARCH 25, 2015 SIMULTANEOUS REVIEW

CN1407-027, IMPLANTED
PUMP MANAGEMENT, LLC
&

CN1411-046, PENTEC HEALTH, INC

1 s	MR. WRIGHT: Yes.
2	MR. AUSBROOKS: Doolittle?
3	MR. DOOLITTLE: Yes.
4	MR. AUSBROOKS: Austin?
5	MS. AUSTIN: Yes.
6	MR. AUSBROOKS: Fleming?
7	DR. FLEMING: Yes.
8	MR. AUSBROOKS: Byrd?
9	MS. BYRD: Yes.
10	MR. AUSBROOKS: Johnson?
11	MR. JOHNSON: Yes.
12	MR. AUSBROOKS: Ten "yes."
13	MR. JOHNSON: The motion passes.
14	The certificate of need is approved.
15	MR. WINICK: Thank you very
16	much.
17	MR. JOHNSON: Thank you.
18	We're about to get into a
19	lengthy part of our agenda, and so we're going
20	to take a ten-minute break before we do that.
21	(Brief recess taken from
22	9:45 a.m. to 10:05 a.m.
23	MR. FARBER: Implanted Pump
24	Management, LLC, Knoxville, Knox County,
25	CN1407-027. This application is for the

establishment of a home care organization and 1 2 the initiation of home health services limited to intrathecal pump services. The parent 3 office will be located at 200 Prosperity 4 5 Place, #102, Knoxville, Knox County. are no branch offices proposed for this 6 The service area includes all 95 7 project. The estimated project 8 counties in Tennessee. 9 cost is \$13,038. 10 This application is opposed by 11 National HealthCare Corporation. This 12 application was deferred from the December 13 2014 meeting. Mr. Mills is recusing on this 14 application. Here on behalf of this 15 application are Melissa Hess and Rachel 16 17 Nelley. 18 The second application, in the 19 simultaneous review, is Pentec Health, 20 Incorporated, Nashville, Davidson County, 21 This application is for the CN1411-046. 22 establishment of a home care organization and the initiation of home health services limited 23 24 to intrathecal pump infusion and IgG replacement therapy services in all counties 25

1 in Tennessee except Hancock, Perry, and Van 2 Buren Counties. The parent office will be 3 located in leased space at 424 Church Street, 4 Suite 2000, in Nashville. There are no branch 5 offices proposed for this project. 6 estimated project cost is \$142,028. 7 This application is also opposed 8 by National HealthCare Corporation, and 9 Mr. Mills will be recusing on this application 10 as well. Here on behalf of Pentec Health 11 12 are Doug Wynd. 13 MR. JOHNSON: Okav. This is a 14 simultaneous review, which is different than 15 any that most of us have experienced. There's 16 been one since I've been on the Agency. 17 maybe Mr. Gaither and Ms. Jordan have seen 18 more, but it's a bit unusual for us. So it's 19 going to be done a little differently. 20 hear the application remarks, the opposition, 21 and then we will get into the member 22 discussion as we normally do as opposed to 23 doing it individually. 24 There is opposition for both --25 I want to make sure that's correct -- right?

1	(Opposition noted.)
2	MR. JOHNSON: All right. So
3	we've got that present. Then we'll go through
4	the process. So first [is] the support
5	presentation.
6	MS. HESS: Hello. My name is
7	Melissa Hess. I'm an RN and Director of
8	Nursing for Implanted Pump Management
9	MR. JOHNSON: I think you need
10	to get the microphone maybe closer, so we
11	can
12	MS. HESS: Closer? Is that
13	better, sir?
14	MR. JOHNSON: (Nods head.)
15	MS. HESS: I'm short. Thank
16	you. My name is Melissa Hess. I'm an RN and
17	Director of Nursing for Implanted Pump
18	Management. I have been working in the home
19	intrathecal management portion for nine years.
20	I actually have a passion for the therapy.
21	I've seen how the therapy can assist patients
22	getting to who are bed bound, writhing in
23	pain to this pump augmenting them and
24	assisting them to really working a
25	40-hour-a-week position. So it really is a

great therapy that you can see tangible results.

I want to explain a little bit about the intrathecal pump therapy, if I can, because I'm not quite sure what knowledge level everyone does have of that today. The intrathecal pump is used for two main reasons: Chronic pain and chronic spasticity. So for spasticity, you could look at diagnoses such as cerebral palsy, traumatic brain injuries, spinal cord injuries, and, in some cases, ALS, and then you have a portion of the patient population who suffer from chronic pain.

These are those individuals that have had several surgeries, and the doctors have said I can't do anything else to fix this; there's nothing else I can do. And these patients are still in an immense amount of pain and it's affecting their quality of life. They're on a plethora of oral medications. They are unable to participate in their everyday activities as they should be able to. So that's another individual who might benefit from one of these pumps. So you look at chronic pain and spasticity as the two

main indicators.

It's important to understand that these pumps don't treat chronic pain and spasticity. They don't look at the underlying issue, but they treat the manifestations; the pain and spasticity. And the goal would be for the individuals to have a higher quality of life, to get them maybe out of a wheelchair into a stander, or it may be as simple as for a caregiver to be able to dress them easier in the morning.

So the spectrum of patients is very large. You look at an individual who, with a pump, can possibly work a full-time position, or you have an individual who maybe, from a wheelchair, can transfer more easily to the bed.

The pump is a titanium pump.

It's a closed system. It is implanted usually in the right or left lower abdomen. And a medication, via a catheter is delivered to the spinal column in that intrathecal space. The mind-set and the rationale for this therapy is that the medication enters the cerebral spinal fluid, it does not cross the blood brain

barrier, and the manifestations of any sort of side effects that any oral medications would commonly take are not generally presented with an intrathecal pump. So the individuals can have better pain relief, better spasticity relief, and not be dozing off; not have those secondary effects of the two types of medications used to treat the chronic pain and spasticity.

The higher quality of life, I think I touched on about five times already, but that really is one of the overall goals of this therapy. And it does require a high acuity. These pumps are not visible from the outside. You could not tell that any of us here might have had a pump. It's not something that any individual can pick up quickly. You have to understand the mechanics, you have to understand how the patient manifests, you have to understand the programming, and you have to really understand the medications and how they affect the patient.

The introduction of intrathecal home care management services to the state is

something that we have found that is required 1 2 and actually deficient in the state of 3 Tennessee. The current model is that these individuals who have pumps go to the doctors' 4 5 offices to have the pumps refilled, to have them increased or titrated, and for any of 6 7 that management piece. What we look at is, the doctors 8 are saturated with the pumps. So for an 9 individual that -- for example, a doctor who 10 11 has 20 pumps, that takes a lot or a huge 12 portion of their staff management to manage. And there are actually patients waiting to 13 have pumps. I've had doctors say to me, "I 14 15 really wish that I could do more pumps, but I just can't take on the additional management. 16 17 So the home care management 18 piece really takes that --19 THE COURT REPORTER: Ma'am, you 20 really need to get in front of the microphone. 21 MS. HESS: Oh, I'm sorry. 22 apologize. I'm moving. I have a little 23 Italian in my. I apologize. 24 I want to go ahead and explain 25 that this introduction of home care management

will allow the physicians to offer the treatment more readily. It would give the individuals better access to care. The nurses would go to the patient's home, they would go to a day treatment center, and sometimes to a place of work. The individuals could be filled in their setting.

And the idea of the home care piece is very important, because individuals, in their home care setting, generally benefit from that. You take away any sort of burden of travel; you take away higher access to care. If an individual needs a request for an increase or a decrease, the nurse, in the IPM -- or Implanted Pump Management -- model is able to get there generally within 24 hours.

That same patient who has had an increase in pain and needs an increase in their intrathecal pump dose may have to wait two weeks, based on the doctor's schedule and also a schedule for them to actually get to the physician's office. So I think that's a really important piece to bring up today.

There is a full RN assessment.

We are there only for the pump. That's 1 2 something I wanted to really make clear. The 3 Implanted Pump Management model is only to fill the pump, to look at the patient 4 assessment, and to do everything in regards to 5 this intrathecal pump. So we're not here to 6 7 offer any other type of skilled services. So the idea of us being 8 introduced into the state will really not take 9 10 away any of the existing licensed home health 11

introduced into the state will really not take away any of the existing licensed home health agencies' resources that they're currently utilizing. I did do, upon the application, a poll of 157 of the licensed home health agencies in the state of Tennessee. And we call them all individually and say "Do you offer this intrathecal home care management?" And one agency said that they were able to, but they have no patients. So I believe that definitely shows that there is a lack of services in this state.

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We do offer 24-hour on-call availability. Our model works with assisting the doctors, assisting the patients, and really working as that liaison between the two.

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I would hopefully like to go over some of the patient benefits that this program -- the introduction of this program would bring to the residents of Tennessee who have intrathecal pumps. We, again, have the 24-hour on-call service. That's very important. They would speak to a nurse who knows the therapy. They're not brought to a They understand that they will call center. speak to a nurse that understands and does this pump day in and day night [verbatim]. The home care approach is more efficacious for the patient due to the location and the availability of the nurses. I spoke about this before. And the idea of the RN doing a

And the idea of the RN doing a full nursing assessment really can lead to a reduction of overall secondary infections for the individuals. If you have an individual who's in the home care setting, who the nurse is there to do a pump refill, and I might identify an area of redness on the right hip. So I would educate. I would let the physician know that we need some more intervention care before we get to a skin breakdown.

A lot of these individuals do have a lot of secondary concerns and problems that are going to arise due to their disease processes, so the proactive approach is very important when we're looking at this model. We are the eyes and ears for the physicians while we're in that home care setting, and we can bring anything to them that we feel is out of the normal. And that is the policy and how we will introduce the system.

I do want to quickly go over the benefits for the physicians, because not only is it a benefit for the patients, but it's a benefit for the physicians and their office. It allows them to really increase the patients that they can service with this intrathecal pump. It allows the increase in modality; it allows the increase of secondary eyes and ears in the home care setting.

And I am going to go over -- I know, in part of the application, there was a question regarding TennCare residents. I know part of the State Health Plan really is specific that TennCare residents need to be identified and any introduction of the model

1 would be required to service those 2 individuals. So Mr. Putrino was hoping to 3 speak quickly regarding Medicare and our pathway that we have developed for that. 4 5 Thank you. MR. PUTRINO: Good morning. 6 My 7 name is Roy Putrino. I am the owner of both BHI and IPM. As a pharmacist, I've been 8 9 providing intrathecal home care services since 10 1991. 11 Our organization has developed a very strong Medicare program. With the help 12 13 of CMS, we've been able to access the MAP 14 programs -- which is the Medicare Advantage 15 programs -- to provide enhanced services to this population. We help -- we assist them in 16 17 finding the proper MAP for them. We also have the MAP companies, like Humana and United, go 18 19 to their home and explain the benefits, and if 20 they choose to go ahead, they can. And at any 21 time, they can revert back to Medicare, if 22 they would like. As a pharmacist, I'm licensed in 23 14 states, one of which is Tennessee. As the 24

owner, I take full responsibility knowing that

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the -- knowing all the specific laws from the state, in the development of all the clinical programs of our organization. Over the last 14 years, my organization has developed a unique clinical program that is both proactive and cost-effective. This model has allowed us to grow to a national level via word of mouth, and it is our desire to bring this model to Tennessee.

regarding the state compounding pharmacies.

And although our organization has a Tennessee pharmacy license and I am a licensed pharmacist, we have no problem in making the use of an in-state compounding pharmacy as a condition of the CON. Currently, we have this model set up. We are currently working with pharmacies in other states, like West Virginia, Ohio, Louisiana. It actually works quite well, and it's great to have the people on the ground.

I understand you have over 200 compounding pharmacies in this state. We'd be happy to find one to work with us. Thank you very much.

1	Oh, Melissa will do the summary.
2	MS. HESS: I believe do we
3	do
4	MR. PUTRINO: Now or later?
5	MS. HESS: Is pro and support,
6	and then summary after?
7	MR. JOHNSON: Pardon me?
8	MS. HESS: The summary is after
9	the other part, because we're doing a
10	simultaneous review; is that correct, sir?
11	MR. JOHNSON: There will be an
12	opportunity right now for people who support
13	the application who are not a part of it.
14	MS. HESS: Okay.
15	MR. JOHNSON: I didn't call for
16	that earlier, but I will now.
17	MS. HESS: Okay. Thank you.
18	MR. JOHNSON: So now is the time
19	to do that. Are there those who wish to
20	speak? Anybody else?
21	MS. HESS: I think it's just us.
22	(None noted.)
23	MR. JOHNSON: I don't think so.
24	MS. HESS: Okay. Thank you.
25	MR. JOHNSON: Mr. Elrod, the
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opposition's presentation? 1 2 MR. ELROD: Thank you, Mr. Chairman and members of the Agency. 3 Dan Elrod, here on behalf of NHC HomeCare, 4 5 which, through its affiliated agencies, operates throughout the state, except for 6 three counties: Scott, Hancock, and Lake 7 NHC is a provider of comprehensive 8 Counties. home care, including infusion therapy. 9 This application, we submit, 10 suffers from multiple deficiencies, including 11 the following: No need has been established. 12 The applicant requests authority to serve 95 13 counties in the state, but readily admits it 14 has no information about how many patients in 15 each county, if any, actually need this 16 Using the Guidelines for Growth as a 17 service. starting point, there is clearly no need for 18 additional home health in the state, and the 19 20 staff report establishes that. In the face of that, it's really 21 22 up to the applicant to show, through 23 documentation, that patients are not being served now; that patients are going without 24 25 adequate service now. And they have

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completely failed to do so. They have produced two letters from physicians -- two physician letters -- one from Nashville and one from Hendersonville, and two patient letters -- one from Lebanon and one from Gainesboro -- none of which say that there's a failure to get service now. They're supportive of the application, but they don't say that they're going without service. we submit that that's not sufficient to establish need in one county, much less 95 counties. The application also fails to meet the criteria of orderly development of health care. The limited service proposed in this application is the fragmentation of health care to the extreme. Patients with intrathecal pumps are medically complex, with comorbidities. And it really defies common sense and it's contrary to where health care is headed to create a model of care that

And this is really kind of highlighted in the application because there was -- there's a real contradiction in the

addresses only one aspect of patient care.

application between what it says and actually 1 2 what was said this morning, because in the application, in one place, they say, "We're 3 gonna take care of the whole patient." On 4 page 46 of the application, it says that it 5 will, quote, "focus on the patient as a whole; 6 not on the implanted intrathecal pump." 7 8 But then on page 43, when attempting to show how this is not going to 9 affect other home health agencies, they say, 10 quote, "IPM focuses only on this one therapy." 11 12 And that's what was said here this morning: 13 "We're gonna only do the intrathecal pump." That's not a good model of health care, 14 15 because it doesn't look at the patient as a 16 It's just a flawed model, we submit. whole. 17 And we appreciate what's being 18 said here in terms of -- about the change now 19 from what was in the application to their willingness to use an in-state compounding 20 pharmacy. We submit that that condition is --21 22 I'm not sure how that would be enforced by the Department of Health or how you would police 23

But in any event, the pharmacy

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that.

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part of this organization has a shaky regulatory history. And this was pointed out in the Department of Health report which summarized numerous violations in other states, including South Carolina, Colorado, and Illinois. And one of the compounding pharmacies that the applicant relied on actually had a problem in Louisiana with a diversion of 22 pints of codeine cough syrup and 10,000 hydrocodone pills. And we're talking about an opiate substance in this situation. This disciplinary history is really a good segue into our final point. that's Commissioner Dreyzehner's letter,

really a good segue into our final point. And that's Commissioner Dreyzehner's letter, which, in my history of doing this in front of the Agency, is unprecedented, in terms of having that kind of letter from the commissioner of health. And, remember, Commissioner Dreyzehner is a physician and he's also a public health expert.

And his letter includes the following concerns: The model of care may not be consistent with the rules relating to the dispensing of controlled substances. He's

concerned about the reliance of out-of-state 1 2 compounding that's been somewhat addressed, 3 but we submit how that would be policed is still uncertain. 4 Commissioner Dreyzehner's letter 5 also notes a recent practice guideline from 6 the American College of Occupational and 7 Environmental Medicine that casts serious 8 doubt on the appropriateness of the 9 intrathecal pump procedure itself. And that 10 article -- that practice guideline --11 12 concluded with this quote (as read): "Thus, 13 with a lack of documented efficacy, invasiveness, serious adverse effects, and 14 15 marked costs, these devices are not 16 recommended." 17 Commissioner Dreyzehner ends his letter of concern with this statement (as 18 19 "On balance, we have concerns 20 regarding the unintended consequences that may result from these services and the overall 21 22 impact they may have on the population and health in Tennessee." 23 One other point I want to 24 25 make -- it relates to the presentation they

1 just made to the Agency -- is that, in the 2 application, it says repeatedly "We're not 3 gonna be Medicare certified," but yet part of the discussion this morning has been how they 4 5 serve Medicare patients. That, to us, doesn't 6 really -- the two statements are not 7 reconcilable, and it certainly needs to be 8 something that's taken into account by the 9 Agency. 10 We submit that we have presented 11 numerous reasons why this application should 12 be denied. It hasn't -- it does not meet the 13 criteria. But, in any event, Commissioner 14 Dreyzehner's letter alone is really a reason 15 for the Agency to deny this application, and 16 we urge you to do so. 17 MR. JOHNSON: Were there others, 18 Mr. Elrod, or is that it, in terms of the 19 opposition? 20 MS. WEIR: Hi. My name is 21 Scarlett Weir, and I work with a company called ContinuumRx Home Infusion. We have a 22 23 joint venture with Saint Thomas Hospital and 24 we service all of those patients, and [we] 25 work very closely with NHC to provide the

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whole continuum of care for patients.
                                            So we
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    are greatly concerned. We do provide
    medications for patients going out of the
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    hospital, be it IV antibiotics, IgG, or pain
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    medicine.
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                  We have a very secure pharmacy.
    It's very controlled. We work with the
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    hospitals and NHC to make sure that the
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    patient -- not only the medication, but the
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    whole service of care for the patient is
    provided. And so we think this would be a
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    very bad idea. Thank you.
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                  MR. JOHNSON:
                                Thank you.
                  Is that all?
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                  MR. ELROD: (Nods head.)
                  MR. JOHNSON:
                                All right.
                                             Now we
16
    have rebuttal, up to five minutes.
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                  MR. PUTRINO:
                                My name is Roy
              I'd like to go over a few of the
19
    Putrino.
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    points.
             First of all, addressing the Medicare
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            Medicare does not cover home infusion,
    issue.
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    so it doesn't cover any, but we try to address
    it. So at this point, you know, saying that
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    we're not a certified agency really doesn't
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    make a difference at this point. So what
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we're looking at here is finding a pathway for these people so that they're not ostracized from this therapy.

As far as the therapy not being efficient, you know, you just have to see a multiple sclerosis person who is rolled up in a pretzel get this pump, and then your mind will change and they are able to start caring for themselves again and move back into society.

What basically brings -- what IPM brings to the table here is something bigger than that though. We have a national network. If this person travels anywhere in the country, there will be an IPM nurse to care for them. Whether they go to Orlando or Alaska or anywhere in the country, we will be there for them.

When you go into an emergency room with a problem with this pump -- and you have over 200 here in Tennessee -- there will be no programer there and there will probably be no person that will be able to handle it. This is why national -- major insurance companies sign national contracts with us. We

are out there protecting these patients. 1 2 In the hospital setting, the 3 patient has to be -- has to travel there. 4 Every time there is an issue, they have to get 5 an ambulette or have a family member to bring them there. We can settle 90 to 95 percent of 6 7 the issues, through our monitoring center, with a simple dispatching of a nurse. 8 been effective for over 14 years, and we have 9 10 been brought all over the country, word of 11 mouth from physicians who have had excellent 12 experiences. 13 And I see the problem where he's 14 saying that the results haven't been good, but 15 our outcomes from the home care piece far exceed those. We have people with reduced or 16 eliminating oral medications, and by not 17 getting the tremendous pronounced side effects 18 19 from some of these drugs, the patient's quality of life has gone, you know, much 20 21 Let's remember there's no cure for higher. these things. We can only look at the quality 22 23 of life. Thank you. 24 MS. HESS: My name is Melissa 25 I was hoping to address some of the Hess.

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concerns from the gentleman, and the woman from ContinuumRx Infusion. I understand the concern that they're worried that these patients are medically complex and that we're there to do one thing. I think I wanted to clarify in my presentation -- I'm not sure if I came across efficiently in explaining that we are there to do a full nursing assessment. We are not going to disregard a wound and we are not going to disregard signs and symptoms of a urinary tract infection, but our model does not do that ourselves. We assist -- we use the physician. We call the physician and say, "This individual has X, Y, and Z. How do you want us to follow up? Do you want to come see them? We think that they may have a urinary tract infection," for example. So the idea for us being there -- we do the pump because it's very specific, but we always look at the whole patient. And I think nursing always looks at the whole patient. I think to go in and look at only the pump and not do a full nursing assessment would be negligence in nursing. The idea that we're there to look at every

aspect of the patient -- it's always very important. It's just that IPM does not service every aspect of the patient.

So I hope that clarifies what I had presented before or that that makes better sense, but our model is to identify any abnormal findings, alert the physician, and the physician will use -- if there's other skilled services required for this individual, the physician will use the existing licensed home health agencies for those additional skilled services. Our skilled services will only be specific to that intrathecal pump. I hope that clarifies that.

And I understand the concern that the model is different. And it is different from a lot of other home care models and medical models. But the fact that these pumps are delivering high doses of morphine, high doses of Dilaudid, very high concentrations of Lioresal, there is no room for error. So as a nurse -- and I think I'm a pretty good nurse. But for me to go in a home care setting to do an IV IgG or to go do a wound care, and then to do a pump, my focus

1 isn't going to be on that pump. And if the 2 focus isn't primarily on this intrathecal 3 pump, errors are going to occur. 4 So the focus is created on the 5 intrathecal pump to reduce and -- I can't say 6 eliminate, but to greatly reduce that error. 7 So I hope that clarifies, also, that model. 8 And ContinuumRx Infusion, the idea of them being a very strong pharmacy I'm 9 10 sure is very true, but do they provide 11 intrathecal medications. When you look at narcotics, it doesn't -- the intrathecal 12 13 medications are so different than oral 14 So I think we have to look at the narcotics. 15 distinction between the intrathecal pump and 16 the rest of the care that the individuals have 17 and require. Thank you. 18 MR. JOHNSON: Okay. Thank you. 19 Okav. Applicant 2's 20 presentation -- I have it listed as Doug Wynd 21 who is going to do that. And we'll go through 22 the same procedure for you as we did for the 23 first one, and then we will get into guestions 24 by the members. 25 MR. WYND: Yes. Thank you.

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Actually, my name is Doug "Wynd," like you
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    "wind" a clock, but 90 percent of the people
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    guess "Wind" and I live with that.
    offense taken. I also have with me three
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    other people from Pentec Health. I, myself --
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    I am the national sales director with Pentec.
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 7
                  MR. JOHNSON: Before you go --
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    are there others that plan to speak as well,
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    in support --
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                  MR. WYND: Yes, sir.
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                  MR. JOHNSON: -- that either are
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    a part of it or those that are not a part of
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    the application?
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                  MR. WYND:
                             Yes, sir.
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                  MR. JOHNSON: Both?
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                  MR. WYND:
                             Not -- the people
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    that are planning on speaking in favor are
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    part of the application.
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                  MR. JOHNSON: [They're] with
20
    you?
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                  MR. WYND: Yes.
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                  MR. JOHNSON: Okay. Please
23
    continue.
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                  MR. WYND: So I have three other
    people from my company with me. I have
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Michelle Hiidel. Michelle is the regional nurse manager. She will be responsible for home health care here in Tennessee if we get the privilege to work here. She is a registered nurse. She's also licensed as a nurse here in Tennessee herself. I have Chip Slavin. Chip is a 15-year pharmacy -pharmacist with Pentec Health. And he can answer and address any of the pharmacy questions that may come up. And then I have Amy Toresco, who is an account executive on our IVIG side of our business that's part of that application as well. So they'll be here to address any questions that may come up in the process.

But we as a company are thrilled to be here in Tennessee before you asking for approval in the CON process. We have had referrals come in to our company -- four patients that are living here in Tennessee -- and unfortunately we've had to refuse those referrals because we are not licensed to be here, and they have found sometimes other companies who would be able to take care of those pumps, but that's outside of our

1 regulatory approval. Ms. Hess did a good job of 2 talking about the therapy itself. I want to 3 talk specifically about the pump. This is the 4 pump that both companies are talking about 5 (indicating). You can see that it's about the 6 size of a hockey puck, and it's a very 7 complicated machine. There's a reservoir in 8 This pump is implanted in the patient, 9 and a catheter is run up through the spinal 10 cord in the intrathecal space of the spinal 11 cord, and then the pump continuously pushes 12 13 out highly concentrated narcotics or antispasticity medication to provide the 14 15 relief to a patient. The target for this pump is 16 about the size of your button -- I don't know 17 18 how many of you have a cell phone. The button on your cell phone is about the target size of 19 20 this pump. And, again, it's implanted under layers of skin and muscle and fat, and it's a 21 very difficult site to access. Every patient 22 that has one of these pumps -- and there's 23 about 80,000 of these pumps in patients across 24

the country. Every patient who has one of

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1 these pumps is committed for the rest of their 2 life or until this pump is removed to 3 continually get this pump refilled. By and large, those refills 4 happen in the physician's office, and he or 5 she will refill the pump themselves, or their 6 7 staff will, but as demonstrated -- and as you 8 can appreciate -- these patients are either 9 wheelchair bound or in severe pain or have to 10 travel great distances to their physician to 11 get their pump refilled. And that creates a 12 burden upon society that Pentec Health can 13 alleviate. We can go make house calls to the 14 patients and refill the pumps there. 15 If a pump runs dry -- if it's a 16 pain pump, those patients will go into 17 withdrawal, which is a miserable experience, as you can appreciate. If the patient is 18 19 being treated for spasticity and the pump runs 20 dry and they no longer get their 21 antispasticity medicine, that can be 22 potentially fatal. 23 So, again, the patients are 24 committed to getting these pumps refilled. 25 Whether we do it in the home or the patients

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are forced to go back to their physician's
office, the pumps will get refilled.
filled improperly -- again, the target is very
        If it's filled improperly and highly
small.
concentrated narcotics are shot into the body
outside of the pump -- that's called a "pocket
fill" in the industry, and that is also
potentially fatal. You get highly
concentrated narcotics that can shut down the
respiratory system and a patient could expire.
              So it's a very risky procedure,
a very specialized procedure, and one that
most home health care agencies, as Ms. Hess
stated, too, they certainly -- a lot of times
they aren't even aware that these pumps exist,
and if they are aware of them, they really
don't want to touch them, because it is a very
high-risk procedure and one that, if you're
going to do this procedure, you really need
the expertise to do that.
              So that's the pump (indicating),
and let me speak to our expertise and why
Pentec Health would be a good person to allow
into the state.
                            Let me just
              MR. JOHNSON:
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1	interrupt you a second.
2	MR. WYND: Yes, sir.
3	MR. JOHNSON: You have a
4	ten-minute presentation, which includes your
5	other folks, so
6	MR. WYND: Yeah. And, actually,
7	they're here to address questions. They're
8	not part of this initial salvo, so this is me
9	and the salvo.
10	MR. JOHNSON: Okay. You're it.
11	All right.
12	MR. WYND: Yeah. But I
13	appreciate that. So Pentec has been in the
14	business for about 30 years. We are the
15	largest provider of home health care service
16	in the intrathecal pump space. We have about
17	2,800 patients on service across the country.
18	We are appropriately licensed in 30 states.
19	We are not licensed here in Tennessee, and we
20	are not seeing any patients here actively in
21	Tennessee. We've been referred patients but
22	have turned them away.
23	Our nurses the training for
24	our nurses is second to none. The nurses that
25	we hire oftentimes have expertise in critical

care before coming to us. Oftentimes, they have experience filling pumps in a physician office. They come to us and regardless of their training and past experience, we put them through a rigorous three-month training program. That is the only training program that's ANCC accredited. "ANCC" is the American Nursing Credentialing Council. They accredit our training programs, so our nurses come out knowing stuff.

In fact, we hired two nurses that came from Medtronic, the manufacturer of this pump, and their previous job was to instruct people how to fill the pump. They went through the training program and at the end, they said, you know, that they learned things that they probably should have known and definitely wished they would have known when they were teaching other people how to deal with these pumps. So our nurses are second to none, in terms of their experience and their training, and we'd be thrilled to be here.

Our pharmacy -- we're held to the very high standards of a 797-compliant

pharmacy. Now, oftentimes, your compounding pharmacies at a local level may not reach the 797 standards. It's just -- they're higher standards than normal non-high-risk compounding, or low risk or moderate risk. 797 guidelines are pretty strict, and we certainly meet those and exceed those in doing some proprietary things in our pharmacy that kind of set us apart in the market space.

But the last thing I'll touch on is the insurance piece. And it was spoken to in the previous presentation about really the orderly development of health care and whether or not a company will provide service to

TennCare patients or Medicare patients. In

our application, throughout -- if you've

17 | read it -- it talks [about] and describes our

18 | philosophy about that and our willingness to

19 | take not only TennCare patients, but also

20 Medicare patients across the country.

Again, we're not in Tennessee so we don't have TennCare-specific patients, but other states who have TennCare-like insurance coverage for patients, we do accept those patients on a compassionate care basis. We

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also accept Medicare patients who may -- you know, as a federal program, Medicare does not cover the home visits of our nurse, so that -- we don't get fully paid for that. So we will provide that on our nickel. We'll go and take care of those patients, because it's the right thing to do.

My national book of business -about half of my business are patients that do not fully pay us. And those are patients that -- elsewhere, outside of Tennessee, other companies are not taking those patients, and we fill that need. And we'll take those patients, because those patients are in great need too. Depending on whether or not they have insurance is really irrelevant to most people in the company. I manage that. From a business perspective, I've got to make sure that we can't just, you know, have all people who aren't paying us. It's a business that I run, but it's something that -- again, half of my business is not patients who fully pay. And that was, I think, a clear difference in the applications before you.

The last thing I'll state is

that -- and we don't have anybody here to support us in person. Like I say, we've got 2,800 patients across the country. Every year, we survey the patients. We ask them for their feedback and ask them if there's anything that we can do better. And we get volumes of information where patients will give us feedback on how thrilled they are with what we do. And anything they're not thrilled about, we delve into that and fix it.

But one thing that came through from a patient -- she had volumes to say about her nurse that she couldn't fit in the small space that we gave her, so she wrote a letter. And I'll just read two paragraphs (as read): "Technically, Connie" -- who is the nurse -- "is a godsend. Having a needle inserted in my abdomen and finding where it has to fit" -- or "go to fit into the pump is not a pleasant process. Connie can put that needle into me, and I don't even feel it. I compare it to the times when somebody at the doctor and somebody else has hurt me with the needle and had to go fishing to find the right spot on the pump." Again, if you're looking for that little bitty

thing -- you're in there and you start fishing 1 2 around until you get in. That is a painful 3 process, I can imagine. (As read) "It may not seem like 4 a big deal to you, but it's a huge thing to 5 I'm already in so much pain that every 6 little thing that avoids pain means everything 7 to me." 8 And then she goes on to say that 9 she was in the process of changing 10 medications, which is often a laborious 11 process, where you have regular visits by a 12 nurse to check or most likely the patient will 13 have to go to the physician office to adjust 14 It's 15 the medication and adjust the response. a -- and they keep a diary through the whole 16 process, and she said that our nurse was 17 18 willing to go make those house calls regularly and volunteered to do so, even though it was a 19 three-hour round trip to go take care of that 20 21 patient. 22 And that patient, who had glowing comments and a glowing response, it 23

aspect of her life in a medical situation that

really changed her life or at least that

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none of us want to trade places with. was a patient that was not a full-paying patient for us. That was a patient that was on my dime. That was something that -- that was a patient -- not knowing the rest of the story that would happen, but that was a patient that elsewhere would not have been treated. And if there are other patients in Tennessee like that, they're not gonna be dismissed out of hand by our company. It'11 be with a full business-enterprise approach to taking on those patients. So that, I think, is the end of my time, and we'll go to the next step. Thank you, sir. MR. JOHNSON: Okay. Mr. Elrod? MS. NELLEY: Rachel Nelley here, on behalf of the applicant who opposes Pentec's competing application. I wanted to bring to your attention -- I'm not sure that your materials included a warning letter from the FDA with respect to Pentec. basically -- let's see. The warning letter was dated March 7th, 2014. You know, during their presentation, they indicated they were a

979 pharmacy, subject to high standards. 1 2 Well, basically, the FDA 3 inspection of the pharmacy, between March 18th, 2013 and April 1st, 2013, found -- and I 4 quote -- "serious deficiencies in practices 5 for producing drug products that were intended 6 7 or expected to be sterile, which put patients at risk," unquote. 163 units of product had 8 to be recalled. Their products -- I mean, 9 their products were produced in an environment 10 11 found to have significant contamination risks. 12 There were adulterated products, again, that had been recalled. 13 They took corrective action in 14 15 response to the initial letter from the FDA, but -- and I quote from this letter (as read): 16 "We acknowledge your action on May 15th, 2013, 17 18 to recall all sterile products that were intended or expected to be sterile, with an 19 expiry [verbatim], that were produced in a 20 certain hood. Your planned corrections do not 21 appear to be sufficient to remedy the 22 insanitary conditions at your firm." And the 23 FDA strongly recommended (as read) "that your 24 25 management immediately undertake a

1 comprehensive assessment of operations, 2 including facility design, procedures, 3 personnel, processes, materials, and systems. In particular, the review should assess your 4 aseptic processing operations." 5 And I think we're all, here in 6 7 Tennessee, very aware of what can happen when 8 an out-of-state compounding pharmacy is used 9 and it's producing and sending to Tennessee, 10 for use in Tennessee patients, unsterile We've seen what this -- what a 11 products. 12 disaster can happen with a situation like 13 this. Again, I don't think this --14 15 this letter is very lengthy. And I don't 16 think it was included with your materials 17 today, but I'm happy to go through, in 18 additional detail, the findings enunciated in the letter, if you want me to. 19 Thank you. 20 MR. CHRISTOFFERSEN: May I make 21 a comment, Mr. Chair? 22 MR. JOHNSON: Sure. 23 MR. CHRISTOFFERSEN: Ms. Nelley, 24 do you have copies to submit to the Agency, 25 for the record?

MS. NELLEY: I have "a" copy
that I can submit to the Agency, for the
record, and I'd be happy to.
MR. CHRISTOFFERSEN: Okay.
Well, if you wish to, whenever you're ready
to, Mr. Ausbrooks would be the one to receive
it.
MS. NELLEY: Okay.
MR. CHRISTOFFERSEN: Thank you.
MR. JOHNSON: Mr. Elrod, for the
remaining time?
MR. ELROD: Thank you,
Mr. Chairman and members of the Agency. Dan
Elrod again, on behalf of NHC HomeCare. This
application has really the same deficiencies
as the IPM application, and maybe even some
more.
Again, no need has been
established. It has not documented the
failure of any patient to get this service.
In fact, in their presentation, they've said
when they've gotten referrals now, because
they can't do business here, those patients
have gotten the service elsewhere. So
patients are getting this service mainly from

a physician's office, and that's the model for -- in which this service is now being delivered. And we submit, based on Mr. Dreyzehner's letter and the concerns he raises, that that remains the best option for these patients.

But if, in fact, there does need to be a home solution for this, it needs to be for a home care agency who is going to address all of the patient's needs, not just this narrow part of the patient's needs. And, again, this application suffers from that same problem with a fragmentation of care. They clearly state that they're only gonna deal with the intrathecal pump, and if the patient has other problems, they'll just send them to another provider. That's not a good model of care.

And with regard to how they have handled Medicare patients -- just to put this into perspective, Pentec is a pharmacy; it's a compounding pharmacy. They get paid for the pharmaceutical part of this, even if they don't get paid for the nursing part of it, so it's to their economic benefit to sell as many

pharmaceuticals as possible. And so the
easier they make that to get to the patients,
then they still come out okay, in terms of the
finances of it.

It's not even a machinary (phonetic) undertaking on their part to provide the pump management for Medicare patients without getting paid. There is a payment mechanism for that.

Finally, there's another financial aspect of their application that's frankly just mystifying. They propose to charge \$71 for a nurse's visit and a so-called per diem charge of \$1,775. And they never really explained what that per diem charge is for. They indicate that patients are going to be seen six times a year, so the total patient charges would be \$11,076.

The IPM application says they gonna charge \$200 for a nursing visit, and each patient is seen an average of 12 times a year, so a total of \$2,400 per year. And the fact that Pentec's per patient charge is projected to be four-and-a-half times that of what IPM charges create -- I don't know. It's

inexplicably, frankly, in terms of why there's 1 2 such a great disparity. 3 But all of that, frankly, we 4 would suggest, undermines any idea that this 5 is more cost-effective than the alternatives, which really are two: One, the physician's 6 7 office and where the physician sees these patients on a face-to-face basis when they're 8 9 getting this highly technical situation for a 10 patient who is very sick and has 11 comorbidities, and if that needs to be 12 supplemented with being seen at home, then it 13 needs to be done by a home health agency who 14 can take care of all of the patient's needs. 15 Commissioner Dreyzehner's letter 16 applies to this application just as much as it did the first one, and that alone really, we 17 18 would suggest, again, would require that this 19 application be denied. Thank you. 20 MR. JOHNSON: Thank you. 21 Rebuttal up to five minutes, 22 Mr. Wynd, or a substitute. 23 Good afternoon. MR. SLAVIN: Μv 24 name is Cliff Slavin. I am the pharmacy 25 manager for Pentec Health in Boothwyn,

Pennsylvania. I'm also a licensed pharmacist 1 2 here, and I want to address the 483 findings 3 that we had a few years ago. 4 We were inspected by the FDA in response to what happened with NECC. They 5 6 inspected us as though we were a 7 CGMP-compliant pharmacy -- or facility, as though we were Merck or AstraZeneca or a 8 9 rather large manufacturer, which we are not. 10 We are not designed -- we were not set up to 11 do large repetitive compounding of 12 multiple-ingredient identical products. 13 So when they came in and inspected us, they were sort of looking at 14 15 us -- it was an apples and oranges kind of 16 thing. Regardless, in all respect to their findings, we did take them seriously and we 17 18 made serious progress in terms of what we've 19 done for corrective measures. The first thing is being a -- establishing a quality unit. 20 21 have our own microbiologist on staff; we have 22 our own in-process testing where we've done 23 initial qualifications, process 24 qualifications, ongoing qualifications of 25 everything that we do. So we did take it

1	seriously.
2	With regard to the product that
3	was recalled, when we went through, as part of
4	our routine maintenance annual I'm sorry
5	biannual surveys of our hoods, we found that
6	we had a laminar flow hood that was leaking
7	outside of the cabinet. It was not in
8	anything that could have affected the
9	sterility of the product; however, the piece
10	of equipment was out of specifications by the
11	manufacturer. The responsible thing to do was
12	to recall the product that was just made in
13	that particular hood.
14	That's all I have to add to that
15	at this point.
16	MR. WYND: Thanks, Cliff. And
17	I'll add just one thing about the product that
18	was recalled. There was 163 units that were
19	recalled with the because we didn't know if
20	there was contamination in the product
21	MS. HILL: Sir, can you state
22	your name, please.
23	MR. WYND: Oh, I'm sorry. Doug
24	Wynd again. So sorry.
25	Those products were recalled,

and we replaced the products on a different side of our business, at the renal side; renal division. Patients received replacement product, and no patient lost a dose because of this recall. The products that were recalled were put on a shelf to see if we could grow out a contamination, and no contamination was drawn out from those products that we recalled.

weren't sure. And we sat it on a shelf, and we did not grow out anything that would cause patient harm, even if it was given to a patient, and no patient was at risk for that issue. And Cliff gave the explanation, as a pharmacist, when the issue is brought up by our competition in the marketplace, we explain exactly what happened, and our customers understand the lingo and they get the fact that our pharmacy is above the standards and they get the whole process and, in fact, will deepen their relationship with Pentec because of the issues being raised and being addressed by us.

In terms of the concerns by

NEC -- or NHC, in terms of the need, when I did say that the patients were referred to us and we couldn't fill them and service them, they were seen by another company, but it was Roy's company with Basic Home Infusion. So Basic Home Infusion is operating here in your state without your agency's approval, without licensure, and that's something that we wouldn't do. We had the opportunity to and we said we're not going to do it, and then those patients found another home.

Other examples where patients were on vacation seeing a daughter here in East Tennessee, their pump was alarming and needed to be refilled, we had to say we couldn't fill that patient because we weren't licensed in Tennessee. And there were other patients who were cancer pain patients being treated in Georgia that were residents of Tennessee, asking us to take care of them when they got home from -- after getting their pump implanted, and we had to refuse those patients. I don't think those patients have found somebody to go to the home, but we would love to be that service provider.

1 In terms of the narrow part of 2 the needs and this being pump-refill specific instead of, you know, why not let a home 3 health agency that can do everything do this 4 instead of just the pump -- and I'll use this 5 analogy: The interventional pain medicine 6 offices that we call on, the nurses who refill 7 the pump oftentimes do the pump refill, and 8 they might do it every week, and they're 9 10 scared to death to do that. And that's part 11 of their job. So they're an interventional 12 13 pain medicine office nurse and they do all 14 kinds of things that are done in 15 interventional pain medicine offices, but they 16 are intimidated by the risks associated with filling this pump and being wrong in doing 17 So to suggest that somebody who doesn't 18 19 have the interventional pain management focus 20 could be kind of an all -- you know, a handy 21 man to do everything is, I think, outside of 22 the understanding of the risks that are 23 associated with this pump. 24 And, frankly, that's probably 25 why, when we interview the home health

agencies and ask them if you're taking care of any patients who have intrathecal pumps, they oftentimes don't know what intrathecal pumps are, because a physician, frankly, isn't going to refer out the treatment of this pump -- or the refill of this pump and the management of this pump without knowing we have the expertise.

Again, there's 80,000 patients who have these pumps, and they're being refilled regularly. And the entire market of our industry, there's about 5,000 patients being seen in the home. The other 75,000 are being treated by his or her physician because that's the -- you know, that's the only option they have. So we can go in there and meet that need.

And then, finally, from an economic model perspective, it was suggested that, you know, why our costs, in terms of the per diem and the overall cost to a payor is so much higher than what IPM is suggesting. What was left out of the IPM presentation is that Basic Home Infusion -- you know, Roy's other company -- would be charging all those other

They would be charging the per diem fee 1 2 that was discussed, an average of \$1,700 3 dollars or so, and all the other fees. There are four main components to the fee collection schedule in this market. 5 There's the medication, so we can make a 6 7 margin on the medication, but if that's all the money we're making, we are losing money in 8 providing this service and having our 9 full-time nurses go to the patient's home and 10 provide the service to them and make those 11 12 house calls. That is a losing endeavor for 13 us, but we are making money on the medication. But we would not stay in business if that's 14 15 all we were doing. The second component is the 16 materials affiliated with the refill. There's 17 18 the nursing time that can be billed separately, and then there's this per diem 19 20 that encompasses everything from our 21 electronic medical records, to our ability to 22 do telepathic medicine, to our ability to do drug utilization reviews, to having our 23 24 pharmacies review the very complicated 25 formulations that are oftentimes required with

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1	these patients, to everything else that we do
2	at the back end that's kind of all
3	encompassing the management of this patient.
4	Those fees are negotiated
5	between a company like Pentec and the
6	insurance company. And we tell them what we
7	do, and they tell us what it's worth to them,
8	and we talk about where we meet in the middle,
9	and that's the value that they place on our
10	service to provide this service to their
11	patients.
12	So I'm sensing that, I think,
13	that was over five minutes in total, but I
14	hope that addresses the questions.
15	MR. JOHNSON: We can deal with
16	that collectively.
17	So questions by the members of
18	either applicant or their folks?
19	MS. HESS: Excuse me. I'm not
20	sure if this is out of order and just let me
21	know if this is
22	MR. JOHNSON: I can't hear you.
23	MS. HESS: I'm sorry.
24	MR. AUSBROOKS: State your name.
25	MS. HESS: Melissa Hess. I'm

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not sure if this is out of order. I was
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 2
    hoping to address something that Mr. Wynd had
    brought up, actually, I think, in his
 3
    rebuttal, but it was a direct -- of impact to
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    Implanted Pump Management and the owner of the
 5
 6
    company, Roy Putrino. Is that something I can
 7
    address now, sir?
                  MR. JOHNSON:
                                I think we'll do
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9
    it through the questions and answers.
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                  MS. HESS:
                             Okay.
                                    Great.
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    Thanks.
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                  MR. JOHNSON: Questions by the
    members? Ms. Jordan.
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                  MS. JORDAN: I'll start with
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               Obviously, the question of need is
    Ms. Hess.
    something that we have to be satisfied that
16
    there is a need that exists. And that's true
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    for both applications. I'm concerned that the
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    application did not include more specifics
19
    about patients who currently have these pumps
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    but are unable to receive this service in
21
22
    their home.
                  MS. AUSBROOKS: Ms. Jordan,
23
24
    speak into the microphone.
25
                  MS. JORDAN: Oh, I apologize.
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1 Tell me why we don't have more information 2 either from patients who haven't been able to 3 obtain this service or --(Microphone turned on.) 5 MS. JORDAN: Okay. Can you hear All right. Why don't we have more 6 me now? 7 specifics in the application, either from 8 patients or from doctors who are using these 9 pumps that this is an unmet need? 10 MS. HESS: Melissa Hess. That's 11 very good question and one that I think I can 12 pretty adequately address for you. One of the main reasons that we don't have even a lot of 13 14 the pump numbers for the volume of Tennessee 1.5 is that the numbers are very proprietary to Medtronic. Medtronic is actually the number 16 17 one pump manufacturer. I think it was 18 Mr. Wynd had said that there was approximately 80,000 pumps in the U.S.; intrathecal pumps. 19 20 I think Mr. Wynd would also probably agree 21 that the majority of them are made by Medtronic; is that correct? And Medtronic is 22 23 a huge corporation, and that information is 24 very proprietary to Medtronic. So we actually did go to 25

Medtronic to ask them specifically how many 1 individuals in the state of Tennessee; can you 2 3 give me specifics regarding counties. that was information that they were not 4 willing to provide to us, for that reason. 5 They felt it was proprietary and that it would 6 allow their competitors to have information 7 that could potentially damage them. 8 As far as the patients not 9 knowing about the service, I think that's 10 really, Ms. Jordan, a lot of times what 11 The patients don't often know that 12 happens. 13 another model, the home care model, is 14 available. Through my experience, they said, 15 I've been going to the doctor for six years, and I didn't even know you could do this in 16 the home. So a lot of the individuals -- and 17 I would assume that that's the way in 18 Tennessee -- they don't know that this is an 19 20 option. So to answer the other part of 21 your question, we have had a lot of interest 22 23 from physicians regarding -- when we go to different conferences, they say: "Well, why 24 aren't you in Tennessee? I have a whole bunch 25

1 I could really use your service. of patients. 2 Right now, I have five that I'm thinking of 3 that have to take an ambulette in to my office 4 to get filled. It just shouldn't have to be 5 like that." 6 So that's really how we compiled 7 some of our data, but it's just -- it's not hard-and-fast data that I was able to provide 8 9 you. I'm not sure if that answers your 10 question. 11 MS. JORDAN: Well, I quess if 12 there are doctors that have expressed that 13 interest, I don't understand why you couldn't 14 have gotten those doctors to write a letter 15 I have five patients that would be saving: better served in their home. 16 17 That probably would MS. HESS: have been a better way. You know, if I had 18 gone through the experience again, I can see 19 20 where that would have been a better effective 21 tool to provide you to show more of a need. Ι 22 was actually scrambling at the end of it. 23 had worked on the application myself, and I, 24 you know, was just struggling to get all of 25 the information together. So, you're right,

that would have been a better way to present 1 it to the committee to show that need. 2 3 MS. JORDAN: Okay. Another Help me understand -- I believe question: 4 your application says that you project 120 5 patients the first year. 6 That's correct. 7 MS. HESS: 8 MS. JORDAN: But yet the application indicates that there would only be 9 one RN in the first year -- but you're going 10 to be serving patients on a statewide basis --11 and each patient would be seen once per month. 12 13 I don't understand how one nurse could serve that many patients per month on a statewide 14 15 basis. You're right. MS. HESS: 16 There's actually another place in the 17 application where it talks about patient 18 caseload. And, ultimately, when we get our --19 our goal would ultimately be 120 patients with 20 a projected volume of around two to three 21 22 hundred patients in the state of Tennessee. Not all of those individuals are gonna be a 23 good fit for home care. There are gonna be 24 some that don't want to use home care. 25

are gonna be some physicians that don't want to use the model. You know, not every physician that works with these intrathecal pumps would be willing to give all of their patients over to a home care model. So that's why our goal would be 120.

Our goal after the first year would be to get 120, but I believe there's also a part -- and I can pull the page up. I don't have it in front of me, Ms. Jordan -- that talks about the census to RNs, and it would be between 40 and 50 patients per RN, based on demographics. For example, a lot of times what we use is a catchment area of between 120 and 180 miles, regarding the nurse's home or central location. So those patients -- any of those patients in that area would really fall into that certain RN's census.

So it's very feasible that if a patient has to be seen, you know, once a month or once every two months, for a nurse to do that Monday through Friday, specifically if they're very close geographically. The actual visit takes approximately an hour or maybe an

1	hour and a half, depending on whether an
2	admission is being done, or if there's other
3	concerns that the patient might have, the more
4	education the patient might need on that day.
5	So it's very feasible for a
6	patient you know, a nurse, excuse me, to be
7	seeing a patient up to maybe three patients a
8	day and still have a pretty full day and get
9	all of those visits required on a weekly
10	basis.
11	MS. JORDAN: Okay. Thank you.
12	MS. HESS: You're welcome.
13	MS. JORDAN: I now have a
14	question for Mr. Wynd. And it's really the
15	same question that I just asked Ms. Hess. Why
16	don't we have more specifics in the
17	application about the need that you assert is
18	out there but is not being met?
19	MR. WYND: In terms of patients?
20	MR. AUSBROOKS: State your name.
21	MR. WYND: Oh, I'm sorry. Thank
22	you. I'm Doug Wynd, with Pentec.
23	In terms of patients stating "We
24	want this service"? Or more specifically
25	MS. JORDAN: Both; both doctors
	ı

1 and patients. 2 MR. WYND: Yeah. So our --SO 3 we are not practicing here in Tennessee. 4 what we find is that when we talk -- if we 5 go to a patient -- and we don't do this 6 anywhere in the country. We don't go to a 7 patient first and say, you know, "Ms. Jordan, we have this great service. And if we could 8 9 see you in the home, would you be interested?" Because that -- by and large, the patients 10 11 would love to have that service, but it also 12 requires a physician referral. 13 And your physician may not be 14 wanting us to do the referral -- or the 15 service in their home. The physicians make 16 money on refilling the patients in their There's great risks associated with 17 office. 18 refilling the pumps, and they -- you know, 19 I've discussed that already. 20 So there's a lot of reasons why 21 a physician wouldn't want our service, but 22 patients, by and large, definitely want our 23 service. So tell me, then, 24 MS. JORDAN:

if the physicians aren't going to refer, then

25

1 how are you going to get those patients? They will refer. And 2 MR. WYND: not all of them, but a good number of them. 3 4 Like I said, there's about 80,000 pumps -patients with pumps in the country, and the 5 industry to see them in their home has about 6 7 5,000 of those pumps. But to every single one of those patients, that changes the outlook of 8 9 their day; of them living with their disease; 10 or the management of it. Whatever it takes for them to 11 12 get from wherever they are, the transportation 13 to the office, waiting for a high-volume office, you know, going through the procedure 14 15 can take, you know, an hour or two, and the 16 travel the roads back home. That whole part of their living with the disease goes away. 17 18 So the patients -- the patients will do that. 19 MS. JORDAN: I understand that, but why did doctors not write letters of 20 21 recommendation saying, as I asked Ms. Hess, 22 "I have five patients that would benefit from 23 this -- or ten patients -- that it would 24 improve their quality of life if they could 25 have this service in their home"?

1 MR. WYND: Right. My judgment 2 was that it would be best to have those 3 letters of recommendation come from Tennessee 4 physicians, and since I'm not here in the market, I was not asking them -- I wasn't 5 6 knocking on their door explaining this service 7 Because some physicians will say: to them. "I love this service. I want to do this 8 9 service. Where have you been all my life," 10 and they'll want to refer patients over. And 11 since we weren't willing to take patients yet, 12 I didn't want those to go elsewhere. 13 Likewise, not knowing the opinion of this committee and the agency -- or 14 15 the licensing procedure, I didn't want to 16 invest the resources to explain that the service exists and get them excited, other 17 18 than what Dr. Muench did. When we met with 19 him here in Nashville -- Comprehensive Pain 20 Specialists -- he was very in favor of it and 21 is supportive of it, and if we get licensed 22 appropriately, he'd be happy to send patients 23 over. 24 MS. JORDAN: I noticed that in 25 2012 your company had a big write-off of

goodwill. Can you explain what brought that 1 2 about? 3 MR. WYND: Sure. Pentec, as a 4 company, has three divisions. A renal 5 products division -- and they basically take care of end-stage renal disease patients who 6 7 are undergoing dialysis. And we provide a nutritional supplementation to those patients 8 9 who are undergoing dialysis. So this 10 write-off was on the other side of the 11 company. The Medicare reimbursement for 12 13 that line of business took about an 81 percent decrease in the reimbursement for our products 14 15 overnight without notice. We thought it was a So we 16 mistake, and it was not. And it stunk. had all the appropriate meetings, all the way 17 18 up to CMS, all the way up to the very top 19 levels, nationally, and had centers involved. 20 But at the end of the day, we 21 took about an 81 percent haircut on our 22 reimbursement on about 80 percent of our line of business on the renal side. 23 So that significant write-off in 2012 was all about 24 25 our reimbursement from Medicare on a very

1	important line of our business.
2	MS. JORDAN: Thank you.
3	MR. WYND: Sure.
4	MS. JORDAN: One more question,
5	Mr. Chair.
6	MR. JOHNSON: Certainly.
7	MS. JORDAN: Mr. Elrod, can you
8	tell me if your client, NHC, has been
9	approached by any physicians for them to
10	provide this service in-home that they've had
11	to turn down?
12	MR. ELROD: This is Dan Elrod,
13	on behalf of NHC. I have actually asked that
14	question myself, and I've been told no, they
15	have not been approached by anybody about
16	providing this service.
17	MS. JORDAN: Thank you.
18	MR. JOHNSON: Other questions?
19	We've got two and I want to ask one as
20	well or three. Let me do mine first,
21	because there's been some discussion about the
22	Department of Public Health and the letter
23	they had written. So I don't know who, from
24	the Department, wants to address it, but you
25	expressed a number of concerns and those are

concerns that I think the members of the Agency might have. And rather than ask individual questions, perhaps you can do that and then we'll ask questions of Health, because it's unusual for us to get such a letter, and so we want to give the Department ample time to respond.

MS. BAYLES: Thank you. Good morning. Julia Bayles, with Health Planning. Jeff sends his apologies for not being able to stay. He had a legislative meeting he needed to attend.

We'd like to start by mentioning the Tennessee Department of Health's mission to protect, promote, and improve the health and prosperity of the people in Tennessee.

And Commissioner Dreyzehner's letter sets out the Department's concerns regarding the unintended consequences that may result from providing these services in the home. As it has been pointed out, they are currently provided in physician offices. But the Department is concerned about the unintended consequences that may result from providing these services in the home, as well as the

1 overall impact it may have on population health in Tennessee. 3 We do have representatives here 4 today from the Department of Health who will 5 state those concerns and can answer your more 6 specific questions. We have Libby Lund, from 7 the Board of Nursing; we have Jerry [sic] 8 Grinder, from the pharmacy board; we have Ann 9 Reed, from Health Facilities; and we have 10 Andrea Huddleston, who is the attorney for the 11 professional boards here today. 12 And so I will now let them come and speak more directly to the points made in 13 the letter that deal with their expertise. 14 15 Would you like to start, Libby? Or Andrea? 16 Whoever would like to start. Andrea 17 Huddleston. MS. HUDDLESTON: Good morning --18 19 or afternoon. I'm not sure, actually. 20 Andrea Huddleston, with the Office of General 21 Counsel for the Department of Health. I 22 supervise an office of attorneys, and we all 23 work with the various professional boards: 24 The Board of Medical Examiners, the Board of

Nursing, the Board of Pharmacy, et cetera.

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And I know, as a group, we were all asked to look at this application. There were lots of things that piqued our interest, and it was an unusual situation and did raise several concerns.

You have the letter from

Dr. Dreyzehner in your materials, I believe.

One of the concerns -- and possibly the

biggest concern -- had to do with the drugs

that are going to be used in the intrathecal

pain management [and] how they're going to be

dispensed and distributed. So that was part

of the concern.

Generally speaking, there is federal law -- and there's state law on this as well -- that pharmacies are to dispense directly to ultimate users; to the patients themselves. And I don't know -- it was never clear to us, I don't think -- and I don't know that it's been addressed today -- if that's what's going to happen. We have some information that that's not the plan and that's not the approach, at least from the IPM entity and perhaps from both.

Our understanding is that these

1 drugs will be shipped to the nurses themselves 2 who will pick them up from Fed-Ex or some 3 entity like, keep them in their homes, and then transport the drugs to the patients. have lots of concerns about that process. 5 We have concerns about the nurses. 6 These are 7 dangerous drugs. These are drugs that end up 8 being stolen and diverted. They have a high street value. And, again, we're not sure that 9 10 that's consistent with federal or state law. If the plan is for the drugs to 11 12 be shipped directly to the patients 13 themselves, that, I think, would probably be a preferable model; however, I think that might 14 15 then involve the pharmacies needing to be 16 licensed as manufacturers rather than 17 Dr. Grinder -pharmacies. (Inaudible off-the-record 18 consultation between 19 Ms. Huddleston and unidentified 20 21 speaker.) 22 MS. HUDDLESTON: I understand 23 for them to ship it to the nurse, they would 24 have to be licensed as a manufacturer, which I 25 don't believe either of these entities are

right now. And, again, under any 1 2 circumstances, there are concerns about diversion and safety in that situation. 3 4 We did not have available to us, at the time, policies related to issues about 5 personnel training and oversight. We've heard 6 7 a little bit about that training, but it doesn't sound like there's an extensive 8 9 training program. And I don't believe we've 10 heard anything about oversight, particularly 11 as regarding drug diversion and drug screening 12 for the nurses who will be perhaps 13 transporting these medications and injecting 14 them. I do believe there has been some 15 discussion about which compounding pharmacies 16 will be used and whether they'll be out of 17 18 At least with the IPM entity, it's understood that there will be an out-of-state 19 compounding pharmacy, in which case our Board 20 21 of Pharmacy inspectors -- they cannot travel 22 out of state to inspect those compounding 23 pharmacies. You've already heard from 24 Mr. Elrod about the recent article and study 25

from the American College of Occupational and 1 2 Environmental Medicine that indicates that 3 these devices are really not recommended, 4 because there are questions about their 5 efficacy. In addition, I believe you have 6 7 heard some comments about whether or not the IPM entity has been operating without a 8 certificate of need and without a license for 9 10 some period. I don't know if they would care to answer questions about how long they've 11

12 been practicing. I know there were questions

13 about numbers of patients and the need for

14 this service, and it seems to me, if they've

already been servicing patients, they probably

have additional information to provide in that

17 | regard.

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So, again, we have Libby Lund, from the Board of Nursing, Ann Reed, from the Board of Health Care Facilities, and Dr. Terry Grinder, from the Board of Pharmacy if you have any additional questions.

MR. JOHNSON: Well, there may be some. We had -- let's see. Dr. Fleming had a question, Ms. Burns, and Mr. Doolittle.

If you have one pertinent to the 1 Department of Health, why don't you ask it 2 3 now. The MR. DOOLITTLE: Yes, I do. 4 5 Pentec applicant says that they have, if my notes are correct, 2,800 patients in other 6 7 states in the United States. Presumably, they 8 are operating under whatever the regulatory 9 quidelines are of these several states. 10 don't think I have any information on that, but in the course of your examination of this 11 12 application and in raising your concerns, do 13 you know of anybody in the Department of 14 Health that contacted other states where 15 either of these applicants provide services to 16 find out, you know, how things work, what the protocols are, you know, regulatory issues, or 17 18 otherwise? 19 MS. HUDDLESTON: Andrea 20 Huddleston, with the Department of Health. 21 I'm told our -- the IPM application came 22 first, and that is the application that we 23 looked thoroughly at. I understand the Pentec 24 application came later. So we have not had 25 any conversations with any other licensing

1	entities across the country to see about
2	whether or not they're using similar models
3	and whether or not they believe those models
4	meet federal and state rules.
5	MR. DOOLITTLE: But as a general
6	point, I mean, in your examination of this
7	business segment, was there any working
8	knowledge of other jurisdictions that allow
9	this, and the pros and cons incurred in
10	MS. HUDDLESTON: For the IPM
11	application, I know there were some
12	conversations with the Massachusetts Board
13	of Pharmacy, I believe?
14	UNIDENTIFIED SPEAKER: New
15	Jersey.
16	MS. HUDDLESTON: the New
17	Jersey Board of Pharmacy.
18	Dr. Grinder, can you address
19	those conversations?
20	DR. GRINDER: Terry Grinder. I
21	am a pharmacist and an investigator with the
22	Tennessee Board of Pharmacy. I have had
23	conversations with the New Jersey Board of
24	Pharmacy, as well as some different offices of
25	the DEA. And as far as the delivery process,

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    the DEA has issued a statement to me saying
    that if they deliver to the nurses, then they
 2
    would have to be licensed as a manufacturer;
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    however, as a compounding pharmacy, they are
 4
    supposed to dispense to the patient.
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                  Now, I was told that there was
 6
    an understanding in New Jersey with their
 7
    local DEA office that they viewed this model
 8
    as more beneficial to the patient, so it was
 9
    basically not enforced there.
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11
                  MR. DOOLITTLE:
                                   Okay. Anything
    else on any other jurisdictions? You know,
12
    general research or otherwise.
13
                                (Shakes head.)
                  DR. GRINDER:
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                  MR. DOOLITTLE: Thank you very
15
16
    much.
                                 Dr. Fleming.
                  MR. JOHNSON:
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                  DR. FLEMING:
                                 Just to clarify,
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    while I really appreciate the commissioner's
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    letter about the issue of efficacy of the
    pump, obviously, in 80,000 instances in the
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    country, the physicians felt that they were
22
    efficacious, because they put them in.
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    mean, so the question of efficacy is
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    debatable, depending on the patient's unique
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situation and unique needs. 1 2 So as a physician, I just want 3 to throw out there that I appreciate their 4 opinions -- and maybe time will tell that they 5 aren't as helpful in the long-term as we think 6 they might be, but if you have one more 7 patient with chronic pain that doesn't have to 8 go to the doctor every month, that's not a 9 small deal, just to throw that out as a 10 commentary. And just from a federal oversight 11 standpoint, these are FDA-approved pumps. 12 They are FDA-approved for implantation into 13 patients for pain control. Correct? 14 DR. GRINDER: Yes. 15 MR. JOHNSON: Ms. Burns. My questions will be 16 MS. BURNS: 17 for Ms. Hess, please. Ms. Hess, can you 18 provide a brief overview of your training 19 program for the nurses? Pentec provided a 20 little bit more of an overview in their 21 application than you did in yours. 22 MS. HESS: Yes. Melissa Hess. 23 Yes, absolutely. I'd be happy to do that. 24 use our training protocol based on Medtronic's 25 quidelines, because, I think as I spoke

1 before, Medtronic is the largest manufacturer of the pumps. And the SynchroMed, which is 2 the Medtronic-manufactured pump really has the 3 lion's share of those 80,000 pumps throughout 4 5 the country. So we really we emulate 6 Medtronic's training. We look at the pump 7 mechanics; we look at the patient; we look at 8 all the medications; we look at refills; we 9 look at programming. You know, everything 10 11 that we utilize to train is straight from Medtronic. And the reason being is because 12 Medtronic made the pump. They have set the 13 quidelines; they had to seek FDA approval. So 14 15 there's no reason for us to change the training as to how Medtronic has set it forth. 16 In addition to that, I have made 17 a lot of extra safety checks in addition to 18 what Medtronic has recommended in their 19 policies for the pump. For example, the 20 21 nurse, if they do any sort of programming other than a simple change in reservoir, any 22 programming out of the norm, the nurse is 23 going to call the on-call nurse and review 24 25 Because the nurses are in the home by that.

themselves. You know, even though we're doing a great thing in the home, we don't have a nurse, as on a hospital floor, to check a heparin drip. We don't have one to run somebody a calculation by. But the model with IPM does offer that. We offer nursing and pharmacist's assistants at just via a phone call.

So part of our training is to really look at how else we can eliminate potential errors. Because nurses are humans, and we have -- we're gonna make mistakes. You know, I can't stand here and, in good conscious, say that I have never made an error, but the safety checks that IPM has in place really make it impossible to leave the patient's house without identifying and being able to fix the error.

For example, we have what's the telemetry. It's a printed version of what the nurse has done to that pump. Once they've read it and if they've done any programming and then updated the pump. Basically, the pump doesn't do anything without us being programmed [verbatim]. So it looks at flow

rate, calculations, and dosages and things like that. It's a huge math equation is what the intrathecal pump really, in essence, is.

So when the nurse is in there doing any programming -- if they're making any changes to the initial programming that was initially read when the nurse got there and read the pump, then what the nurse does is to review, line by line by line, that telemetry. And that sounds very simple, but for me to go through every line -- and there's, I would say, you know, 50 lines -- it's reviewed with the patient or it's reviewed with the caregiver if the patient isn't able to really cognitively understand the review.

So as a last line before that nurse walks out of that house, the IPM nurse reviews every portion of that telemetry to make sure it's perfect. And if, by a slim chance, you know, the reservoir volume should have been 19 and for some reason I push 17 because the lighting is dim, that's found then. So we have that chance.

We also review all of the medications with the patient. We look for

1 color, we look for clarity, we look for 2 concentration, we look for concentration, we 3 look for any sort of sediment. It's reviewed 4 with the pharmacy when the nurse gets to the 5 patient's home. 6 So we have a lot of actual 7 safety checks. And really what we teach our nurses at the very end of it -- I'm not sure 8 9 if anyone is a nurse here -- as a nurse, if 10 there's anything -- any portion of you that 11 doesn't think something is right, they're 12 instructed to stop. And that sounds really 13 basic, but everything has to be perfect. 14 And I think I said it before: 15 There's no room for error with this therapy. 16 We're looking at a catheter -- I mean, an access port, roughly, I'd say, usually, the 17 18 tip of a pencil head or a pencil eraser. 19 everything has to be exactly the way it should 20 be expected, and if it's not, the nurses stop. 21 MS. BURNS: So what is the 22 length of your training before you actually --23 MS. HESS: The length of --24 MS. BURNS: -- have a person go 25 out?

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MS. HESS: Using three to six Yeah. And weeks, depending on the nurse. then, you know, some nurses need longer. And then I'll be honest with you: Some nurses just never fully get what I need them to get. But it's definitely three to six weeks. And. you know, for the first week, it's book training. They have to understand every component of the pump. They have to understand why there's a .22 micron filter in the pump. They need to understand not just the refill procedure but how it works with the And they need to understand the patient. potential red flags that could occur with this therapy. Every once in a while a catheter will become dislodged. So if a patient has had a couple of increases and they're not getting pain relief, the nurse needs to sit and do some critical thinking and call the

doctor and say: "Geez, I've just done two 10 percent increases and they're still at a seven. I think maybe, you know, we're gonna recommend they come in and see you, because I think something -- I think you want to look at

So that's really what our nurses 1 this more." 2 are trained to do. (Inaudible off-the-record 3 consultation between Ms. Hess 4 5 and unidentified speaker.) MS. HESS: (Directed at 6 7 unidentified speaker.) Yeah. Good call. 8 Thank you. 9 I also want to just let everyone 10 know the training protocol, once the nurses 11 we've actually graded the level of access for 12 our pumps. You could have a bump, ma'am, 13 Ms. Burns -- and you're lean, you know, so a pump could be visible. And then a doctor 14 15 could put a pump in an individual who has a 16 little bit more adipose tissue in this 17 abdominal area and you don't even know it's 18 there. So the level of difficulty plays a 19 huge factor on the success of -- of 20 successfully accessing these pumps. 21 So IPM has graded them -- Level 22 1, 2, and 3 -- and that's based on palpation, 23 it's based on being able to palpate all three 24 sides, depth, and things like that. So until 25 the nurse is able to go fully on their own,

1 they have to be witnessed three times with 2 each access level. And that's something we've 3 added on, in addition to Medtronic. MS. BURNS: Another question: 4 How frequently do you actually see the 5 6 patients? Mr. Elrod pointed out that you had 7 said 12 times a year and Pentec said six times 8 per year. So how many times are patients 9 actually seen? 10 MS. HESS: Good question. I'm Melissa Hess, again. Sorry. Well, really it 11 12 depends on the patient and how long they've had their pump. I don't like a patient to go 13 more than two and a half, three months without 14 15 seeing a nurse, because they have that full nursing assessment if there's some things we 16 If a pump is new, it could be 17 didn't catch. 18 every week. If a pump has been established, it could be every two months based on, again, 19 20 medication concentration and the volume of the 21 pump and the daily dose. So I estimated 12. Some 22 23 patients are gonna be under; some patients are 24 gonna be over. But that was my estimation, for that reason. A newer pump really is gonna 25

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take more time to what we call titrate it or to get to a therapeutic level, and when you're dealing medication directly into the spinal column, you really want to go slow.

So a doctor in a doctor's office might say, "Ms. Smith had a really hard time getting here. I'm gonna go ahead and do a 30 percent increase, because she's here," but an IPM model I could have a nurse go every week and do a 10 percent increase and maybe she only needs a second one because we brought her pain level down two points which was our therapeutic goal to begin with. So the model is a little different, but -- I hope that answers your question.

MS. BURNS: And you have, but I guess my concern is, based on Ms. Jordan, you're not planning on having a lot of nurses, and you're covering 95 counties. I can't imagine that you could go see a patient every week. And then that begs the question, as far as patient assessments: Seeing a patient every month or two months, to me, is really not giving a full assessment of the patient versus a home health agency, routinely -- you

know, patients are seen every week. So just a 1 2 little bit of contradiction there, you know, 3 is what I'm seeing there. And I don't know if you or 4 Mr. Putrino need to explain your actual 5 process -- the Department of Health brought 6 7 this up -- you know, the transporting, the dispensing, the pharmacy consultation, the 8 9 administration; just that whole process. I really have a lot of concern and questions 10 11 about that. MS. HESS: Yeah. Absolutely. 12 MR. PUTRINO: Let me do that. 13 MS. HESS: Oh, okay. 14 MR. PUTRINO: Hi. I'm Roy 15 Putrino. First of all, in addition to the 16 nursing, this is not training that the nurses 17 would get in the doctor's office, so you'll 18 have a higher skill level in the home, and, 19 also, all of our nurses get follow-up training 20 every six months. So they must come to New 21 Jersey, and they must go through the training 22 again and again, and we look for little flaws. 23 As far as the distribution of 24 25 the drug, this is a highly sensitive drug.

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There's no preservatives in this. So anybody,
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    if they open that box -- if I send it to the
 3
    patient's home and they leave it in an exposed
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    area, it could be a problem. Now, here in
 5
    Tennessee, they want us to send it to the
 6
    patient's home. We have already wrote that
 7
    policy, and it's in the application.
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                  So we have already complied with
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    that. We feel it's perfectly acceptable, and
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    it will be sent directly to the patient.
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    still a doctor's order, and we will be
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    delivering it on, you know, an as-needed
           So they won't be sitting there with
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    three prescriptions. They'll be -- it'll be
    time for their refill in maybe a day or two,
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    so it'll be delivered to their home.
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                                           But if
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    we use an in-house -- in-state pharmacy, that
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    procedure will be even easier.
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                  Did you want to say something?
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                  MS. HESS:
                             Yeah.
                                     I was just
21
    hoping --
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                  MR. PUTRINO:
                                 [This is] Melissa
23
    Hess.
                             Yeah. I'm Melissa
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                  MS. HESS:
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           Ms. Burns, I was hoping -- I should
    Hess.
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have said this before, and I apologize -- to expand on the training and to just maybe give you a better understanding of the level of training that the IPM nurses have. doctor's office nurses are wonderful. know, they look at a lot of different therapies, and they run back and forth all day long, but they don't have the knowledge level that the IPM nurses are gonna have, just because they aren't able to focus on it like the IPM nurses do. The idea of the sole focus with the IPM model, I think, is really one of the most important things that we do. The idea of understanding all those mechanics, like I talked about, understanding the three levels, understanding the medications, understanding

18 the potential red flags. The doctors -- the

nurse in the doctor's office, and even

20 | sometimes the NPs and the PAs, they can't

immerse themselves in it like an IPM nurse

22 | can.

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So I think that's really, really important for me to bring up; that, you know, patients can go into a doctor's office and

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sometimes, you know, we can run doctor -- the
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    programming. You know, I have often gone in
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    and helped the doctor do the complex
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    programming. Just because I have the luxury
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    of doing it Monday through Friday, and I
    happen to love it -- but also they, you know,
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    the doctors, do just a small portion of this,
 7
    generally, in their practice -- that the level
 8
    of nursing and the level of expertise that IPM
 9
10
    can bring can really be invaluable. So I hope
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    that helps.
                 Thanks.
12
                              Back to, I guess,
                  MS. BURNS:
    Mr. Putrino -- I assume you'll come back and
13
    explain the dispensing and the pharmacy
14
    consultation that's required in Tennessee and
15
    that type of thing. Just explain the process
16
    for that, please.
17
18
                  MR. PUTRINO:
                                 Well, the
19
    pharmacy --
20
                  MR. AUSBROOKS:
                                  Please state
21
    your name.
                  MR. PUTRINO: Oh, Roy Putrino.
22
    The pharmacy has just received, from the Joint
23
24
    Commission, the consulting dispensary
25
    accreditation, just this month.
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pharmacists and nurses in our monitoring 1 2 center work very closely with the physicians on tailoring these prescriptions. We also use 3 the input from the patients. So we are 4 constantly on the phone with them determining 5 what levels of pain they are having, what was 6 7 their reaction from the last changes, and 8 along those lines. We monitor their oral 9 medications as well, and we also are -- we 10 also work with the PTM machines -- which is 11 12 "Patient Therapy Manager" -- which is 13 basically the bolus piece of this external 14 pump. Basic Home Infusion programs it, marries it to the pump, and monitors it so 15 that we can go ahead and, you know, use that 16 to determine the basal rate of the therapy and 1.7 how many boluses they should be having. 18 So there's a lot of consultation 19 going back and forth. And we didn't really 20 21 apply for that consulting degree 22 accreditation. They came back with it to us. And so as far as dispensing, again, to 23 Tennessee, which is the only one that actually 24 25 requires us to go to the -- send it to the

1 patient's home, we're more than happy to do 2 But I just want to forewarn you that this is a preservative-free item, and it goes in 3 the spinal cord. 4 You know, my nurses will have in 5 their home a particular safe area, that 6 we supply with cabinets, where that stuff will 7 8 be stored safely. Even before they go to do it -- to do the refill -- they must call the 9 pharmacy and go over each piece again over the 10 phone as the final check. So there's a lot of 11 12 things that get involved there, but we'll do it from the home. We'll call from the home 13 when we get there and make sure that 14 15 everything is done properly. That's really the whole scope. 16 Is there something -- was there something 17 18 else? MS. BURNS: That's okay. 19 20 just -- you know, routinely, when you go in and pick up a prescription, you know, [they'll 21 say], "Are there any questions?" and the 22 Is pharmacist is available to answer that. 23 the doctor providing the overview of the 24

medication prior to the patient even --

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them.

MR. PUTRINO: Well, the doctor definitely introduces the situation -- so the pump; a change of drug; a change of a combination drug -- and you have to remember that of the seven drugs that we use, only three are approved by the FDA. And of those three, once they are put into combination with other drugs, they are also off label. So over the 14 years that I have been doing this therapy, since the early trials in '91, we have compiled tremendous data; compendiums of them. So physicians feel it necessary to call us even when it's not their patient on conversions from morphine to fentanyl; the ingredients that can be mixed with them; what are the increased gradients; what are the boluses. So we have a lot of data, and we've even taken it a step further. now drawing back what's in the reservoir, taking it back to New Jersey, and we're doing stability testing, which is going to be coming

> MESCHELLE MANLEY DEEN, LCR, CCR 256-303-3362 - manleydeen@yahoo.com

we're already doing that, so we can go back to

Since there's no compendium that will

down, I think, in the 800 Standards.

1 tell you the stability of this -- if I mix two 2 drugs together that are 60 days and 60 days, 3 it's -- you know, some people think it's 60 days, but it's not. It's more like 40 days. 4 And we have now the methods 5 6 with -- you know, with analyzers and mass 7 spectrometers that will now tell us the stabilities of these drugs, and we're giving 8 9 that information back to the physicians. what we're seeing is even better outcomes, 10 because, now, what they thought was hopeless 11 12 was the fact that the drug wasn't getting 13 there and they were, in their minds, thinking, "I have 20 cc's. That's good for 100 days" --14 15 because that's the volume -- but it was really 16 only good for 40. And one by one, people are 17 dropping off of Percocet and all of the other 18 oral meds; even the baclofen. You know, that's really where we found that from. 19 MS. BURNS: Okay. 20 MR. PUTRINO: 21 Thank you. 22 MS. BURNS: And changing subjects now, can you explain your charges? 23 24 Mr. Elrod, again, pointed out that your charges appear to be much less than Pentec's. 25

Can you --

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MR. PUTRINO: Yes, they are. We don't bill for materials, first of all. It's all included in our per diem. Unlike our competitor, all are -- I'd say 90 percent of our cases are all under contract, which means the prices are dictated to us. They're much lower than carving out. And I don't know if you know what that term means. It means that if you don't have a contract, you go out of network and you bill outside of there.

what we bill, but we are under contract with -- our organization is under contract with all of the major insurance companies: -- Humana, United, the Blues, Aetna -- and the reason that they have chosen us is that our model works. Our hospitalizations on our census is 0.2 per year compared to whatever theirs are, and some vary from two to three times a year. So we're going in the hospital once a year, and they're going in the hospital two or three times a year. So that model drives those insurance companies to say:
"Let's take this regional contract and make it

1	national." And that's exactly how this rolled
2	out for us.
3	You know, we realize that it's
4	more than just filling the pump. It's
5	everything around it. And I want to address
6	what the gentleman said there regarding not
7	having a full picture. We do have a full
8	picture, but we don't want to impact all of
9	the other agencies in this state or in any
10	state. That's why we bring them in when there
11	are issues. And they are the experts in those
12	issues, and that's why we bring them in.
13	They know how to handle wound
14	care, and UTIs, and things like that. We are
15	focused on this, but our nurses do a full
16	assessment. But other than that I'm sorry.
17	I went off topic there.
18	MS. BURNS: All right. I'm
19	almost through.
20	Mr. Wynd, please.
21	MR. PUTRINO: Thank you.
22	MS. BURNS: Thank you.
23	MS. HESS: Can I I'm sorry.
24	I'm not sure if this is the time
25	MR. AUSBROOKS: State your name.

MS. HESS: Melissa Hess. 1 Sorry. 2 I was hoping -- it really ties into the training. I was hoping just to get another 30 3 When Mr. Wynd had spoke regarding 4 seconds. doctors wanting them -- Pentec -- to come to 5 Tennessee and they're not able to -- that, you 6 know, Roy was seeing patients in that area --7 how that rolled out is that a doctor's office 8 oftentimes don't have the training, the 9 nursing staff, to really effectively assist 10 They have often sometimes 11 these patients. 12 inherited them from doctors who have retired, or who have left the area, and they're really 13 trying to help the individual, but they don't 14 have the resources to do that. 15 So in that situation, what Roy 16 and Basic Home Infusion did decide to do was 17 to use an independent contractor, in addition 18 to the MD needing the services. So I was just 19 hoping to clarify that. I didn't want that, 20 like, a big elephant in the room, because, you 21 know, our goal to be here for IPM is to really 22 introduce this and to be effective and to work 23 within your State Health Plan. Thank you. 24 25 MS. BURNS: Thank you.

1	To a second seco
1	Okay, Mr. Wynd.
2	MR. JOHNSON: Do you have
3	others?
4	MS. BURNS: For Mr. Wynd.
5	MR. JOHNSON: Oh, okay. I'm
6	sorry.
7	MS. BURNS: So you've heard IMP
8	talk about the availability to use compounding
9	pharmacies within the state of Tennessee.
10	Have y'all considered that or are you still on
11	using the out-of-state pharmacies?
12	MR. WYND: Hi.
13	MR. AUSBROOKS: State your name.
14	MR. WYND: Doug Wynd. No. We
15	have not considered that. And, most likely,
16	we would not entertain that model. We feel
17	very confident in our delivery system. And
18	Cliff can talk more about that, if you're
19	interested in how we particularly do it and
20	how our nurses are an extension of our
21	company and our pharmacy.
22	So the regulations who state
23	that you have to deliver it to the end user in
24	a state, through our legal advice, through the
25	channels and the regulatory processes that we

have asked, you know, about our model -- about 1 2 our nurses, you know, hand-delivering it to 3 the patient and saying, "Here's what it is, this is what I'm gonna do, and that's the 4 delivery of the medication to the patient" --5 that's been sufficient. 6 And, frankly, in the industry, 7 the idea to ship the medicine to a patient and 8 then have the patient brown-bag it back 9 into -- either to the physician's office or to 10 have it waiting there for a nurse to show up 11 to inject it is fraught with high levels of 12 13 concern. So everything from diversion, obviously, to the product becoming riddled 14 15 with all kinds of infection or contaminants, 16 and you just -- you lose control of that 17 thing. 18 So while there may be some bodies that suggest that's a right way to go, 19 20 regardless of whether it's a physician -- and, frankly, the patients themselves -- the 21 22 patients don't want highly concentrated narcotics in their house, because they live in 23 24 the wild. They live wherever they live. And 25 if people know that there's highly

concentrated narcotics with street values of who knows what, that then subjects them to safety risks.

And so we heretofore have not considered that, and those would be our initial concerns with doing a brown-bag situation with these types of medications for those patients. We'd be happy to, you know, discuss that further, but I think that's where we will probably net out, because that's, again, in the industry, brown-bagging these medications. And having it sit around in uncontrolled situations, you lose that, especially in light of the fact that our model, where our nurses are an extension of our pharmacy delivering it to the end user, kind of settles that issue.

MS. BURNS: Okay. And one more quick question for you, and then I want to ask Mr. Grinder and Ms. Huddleston what their thoughts are on that. You have in your application that Coram had announced recently that it's discontinuing this service nationwide. Do you know why? Would you have any comments on that?

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MR. WYND: They didn't state publicly -- well, now off the record, now on the record [verbatim], it's because it wasn't profitable for them to reach the critical mass to do. Everything it takes to manage these patients appropriately, even from the pharmacy level, to do all the things that Roy just spoke to in terms of the calculations and the medications and all the background knowledge that is required of a pharmacy, just to create the medication -- an appropriate medication, to go in the syringe -- is a challenge. And then to have the nursing staff -- if you don't have the nurses that have enough patients to do this regularly, it's a very intimidating procedure, not only just to find that little bitty access port but to inject the medication, hoping that you're in the port. And if you're not, you could -you're looking for signs of, you know, respiratory distress. And then when you push the "Go" button on the program -- you know, you have to program everything in and then you hit "Go," and if you didn't do that right and if you don't have the expertise to do that

1 every day, it's very intimidating. 2 So off-the-record comments from 3 the Coram folks that I have spoken to at the 4 national level, they have said that that's why 5 they're getting out. 6 MS. BURNS: Okay. Thank you. 7 And I just wanted to give Dr. Grinder or 8 Ms. Huddleston either one an opportunity to 9 respond to that in regard to medications being 10 dispensed to the home versus to the nurse. 11 MS. HUDDLESTON: Andrea 12 Huddleston, for the Department of Health. 13 Yes, diversion from the patient is always a 14 That's the traditional model, of concern. 15 The patient goes to the pharmacy and course. has oxycodone pills dispensed; takes that home 16 17 and puts it in their medicine cabinet. Obviously, that's the 18 responsibility of the physician to educate the 19 patient about that concern, and we're -- I 20 think the pharmacists, as well, probably try 21 22 to engage in education about that. But when you dispense to the nurse, now you've added 23 24 another way for diversion, and in multiple 25 levels, I would imagine.

1	I'm not sure, again, how the
2	drugs get to the nurse and then how the nurse
3	keeps them. I've heard some conversation
4	about that, but I've also heard from some
- 5	other folks that perhaps the nurses are just
6	told to generally speaking, that they
7	should just secure them in their home and are
8	not provided appropriate facilities to do
9	that. And then, of course, when the nurse is
10	transporting the drugs in their car. There
11	are multiple levels of diversion danger there
12	as opposed to just the patient having the
13	drugs at home.
14	MS. BURNS: Okay. That's all.
15	MR. JOHNSON: Dr. Fleming, and
16	then Ms. Austin.
17	DR. FLEMING: I've got a quick
18	question for the NHC HomeCare folks. Is there
19	anybody in your home care agency with the same
20	level of training and comfort to do this care
21	in the home?
22	MS. OWENS: Pam Owens, [with]
23	NHC HomeCare. We haven't had any call to
24	train our nurses or to I've just started
25	investigating, with these applications, this

1 whole provision of this service. But not at 2 this time; we don't have anybody. 3 MR. JOHNSON: Ms. Austin. MS. AUSTIN: This question is 4 for IPM. Can you-all speak to the accusation 5 of your company already servicing patients in 6 7. Tennessee without -- [with] the lack of a CON? MS. HESS: 8 Absolutely. My name 9 is Melissa Hess. IPM is not seeing patients at all in Tennessee. But I think I tried to 10 explain that before, and I apologize if I 11 12 didn't do it succinctly. 13 Basic Home Infusion, who Roy is 14 also the CEO of -- and, I believe, a 70 15 percent owner -- does independently contract 16 with a nurse and a couple of physicians in 17 Tennessee for the provision of intrathecal 18 services. But IPM isn't, no. No, ma'am. And 19 that would be against our plan, definitely. 20 Thank you. 21 MR. JOHNSON: Mr. Doolittle. 22 MR. DOOLITTLE: Just a couple of 23 quick questions, starting with Mr. Elrod. 24 don't think I heard you say that NHC provides 25 this service; is that correct?

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                  MR. ELROD:
                               Oh, no. And, in
 2
    fact, I think we made it plain that we don't.
 3
    I'm sorry. Dan Elrod, on behalf of NHC.
 4
    Ms. Owens just answered Dr. Fleming's
 5
    question, that they have not had any calls to
 6
    do so, so they haven't done so.
 7
                  MR. DOOLITTLE:
                                   Got it.
 8
                  MR. ELROD:
                               Right.
 9
                  MR. DOOLITTLE:
                                          The first
                                   Okay.
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    application indicates that there are about 300
11
    users of these pumps in the state of
12
    Tennessee. And I'm going to ask the other
13
    two, but is there any reason to believe that
14
    most of those are done somewhere other than
15
    the physician's office? I mean, is there
16
    obviously another company floating around
17
    whose name hasn't been mentioned today?
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                      MR. ELROD: I don't think
19
    so, Mr. Doolittle. I think the physicians'
20
    offices are where they're being done. And
21
    it's interesting, on that point, that the
22
    Pentec application actually listed five groups
23
    of physicians, including four neurology
24
    groups, that they had been in contact with,
25
    and yet they could produce no letters from any
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1 of those physicians documenting that somehow 2 these patients weren't getting served. 3 think it is happening in physicians' offices, 4 basically. 5 MR. DOOLITTLE: Okay. Well, 6 what I want to focus on very quickly is the 7 economics of this. Do you have any way of 8 estimating what it costs to provide this 9 service in physicians' office? Because we 10 have, you know, apples and oranges comparisons 11 in the application, which I'm going to get to 12 with the other -- with the applicants in just 13 a second. 14 MR. ELROD: We don't have any 15 information about what the physicians' charges 16 are. No, we don't. I'm sorry. 17 MR. DOOLITTLE: Okay. Thank you 18 very much. Ms. Hess -- economics, 19 20 quickly -- the number that I see in the 21 application is a \$200 fee, and it specifically 22 excludes the cost of the compounding. 23 then I think in either your testimony or the 24 other gentleman's, you mentioned that it -- it was mentioned a per diem. Add it all together 25

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    and tell me what the aggregate cost is per
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    visit on an average basis.
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                  MR. PUTRINO: Well, let me --
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                  MR. AUSBROOKS: State your name,
 5
    please.
 6
                  MR. PUTRINO:
                                 Roy Putrino.
 7
    me just begin by saying that this is a wide
    spectrum you're asking, because it's not just
 8
 9
    the refill. It's all of the other pieces
10
    around it: The hospitalizations, the
11
    emergency rooms, the transportation.
                                           So you
12
    have to get all of those numbers together.
                                                  Ι
13
    don't think that UnitedHealthcare would have
14
    given us a contract if it wasn't
15
    cost-effective at this point.
16
                  So for me to answer that
17
    question, I would have to get stuff -- a lot
    of stuff here, but I don't -- I mean, Humana,
18
19
    as well [as] BlueCross, I don't think they
20
    would engage me if it was going to cost them
21
    more money.
22
                  MR. DOOLITTLE:
                                  Well, here's the
23
    issue:
            I am one of three consumer reps on
24
    this panel.
25
                  MR. PUTRINO:
                                 Okay.
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1	MR. DOOLITTLE: And so I am, of
2	course, concerned about consumers, about the
3	payors, and the cost of health care in the
4	state. I am going to try to get an estimate
5	of what it costs to have this done in a
6	doctor's office. Your opposition over there
7	has given us a number which I think is
8	something on the order of \$2,343 as an average
9	cost. So what I'm trying to find out is, it's
10	not 200 versus 2,300 or whatever the correct
11	number was
12	MR. PUTRINO: That's correct.
13	And we're
14	MR. DOOLITTLE: Give me a zip
15,	code.
16	MR. PUTRINO: Okay. Probably
17	about half, I'm gonna say, because we don't
18	have the same per diems. My per diem is
19	contracted, so it's much lower. So we work
20	within the realm of that.
21	MR. DOOLITTLE: Okay.
22	MR. PUTRINO: So we don't really
23	have those higher per diems.
24	MR. DOOLITTLE: I got it.
25	MR. PUTRINO: Oh, sorry.
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MR. DOOLITTLE: Yeah. I'm not
1
2
    pointing fingers.
3
                  MR. PUTRINO:
                                No.
                                      I understand.
 4
                  MR. DOOLITTLE: I'm just trying
5
    to get apples and apples and apples.
                  MR. PUTRINO: I'm sorry.
6
7
                  MR. DOOLITTLE:
                                  And I'm missing
    the physician piece, but --
8
9
                  MR. PUTRINO: Yeah.
                                        I don't
    have the physician piece. And, you know,
10
11
    there's a study being done now called "The
12
    Burden of Care, " and there's a lot of stuff
13
    that the physician does that doesn't get paid
14
    for.
15
                  MR. DOOLITTLE: Let me ask
16
    you --
                  MR, PUTRINO: Like the
17
18
    oversight.
                  MR. DOOLITTLE:
19
                                  Let me ask you
20
    one other additional questions. What other
    states would this sort of service be much more
21
22
    pervasive, since it doesn't exist, to any
    great extent, in the state of Tennessee?
23
    know, what are the other states -- whether or
24
    not you all are there, because I'm gonna ask
25
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Mr. Wynd the same thing -- what are the other 1 2 states that we could benchmark our information on this? 3 MR. PUTRINO: West Virginia; 4 5 mostly if you went to the northern states, 6 because, apparently, multiple sclerosis seems 7 to be in the colder areas. More densely populated areas, like Chicago, New York City, 8 9 Philadelphia, those kind of areas, it would be 10 even more. 11 MR. DOOLITTLE: So you would say 12 that those -- you know, you could hold those states out as where this is a more routine 13 service than it is in the state of Tennessee? 14 15 I would say it's MR. PUTRINO: more common. It's still an orphan therapy. 16 All right. Got MR. DOOLITTLE: 17 18 Thank you very much. it. MR. PUTRINO: You're welcome. 19 20 MR. DOOLITTLE: Mr. Wynd? 21 MS. HESS: I was just -- this is 22 Melissa Hess. I was just hoping to add something onto what Roy said. When you look 23 at the cost at their doctor's office, we'd 24 25 also have to remember not just what the

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doctor's office bills, but the ambulette that
 1
 2
    the individual has to take to and from their
    home to have that done. So there are a lot of
 3
    other costs that are involved with the MD
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 5
    office model that are very hard to
 6
    extrapolate. So I just wanted to bring that
 7
    to your attention.
                  MR. DOOLITTLE:
 8
                                   No. I
 9
    appreciate that.
                  MS. HESS: Thank you.
10
11
                  MR. DOOLITTLE:
                                   Unfortunately,
12
    we don't have that information. But, you
    know, $1,500 per diems -- I mean, the nurses
13
14
    could be riding in limos.
                  MR. WYND: They are not.
15
                  MR. DOOLITTLE: Or flying in
16
17
    private planes.
18
                  Mr. Wynd?
19
                  MR. WYND:
                              Yes, sir.
20
                  MR. DOOLITTLE:
                                   Is my $2,343
21
    estimate -- or your average in your
    application -- is that an all-in number?
22
23
                  MR. WYND:
                              Doug Wynd, with
    Pentec Health. It is an all-in number, and if
24
25
    that number varies from -- we gets zero
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reimbursement for providing the exact same 1 2 care with the exact same medication to 3 probably in excess of that, depending on what 4 the insurance company deems the value of the 5 services that we're providing to be for their 6 particular patients. So they figure out what 7 it's worth, and they tell us what they're willing to pay for it, and then we reach an 8 9 agreement as to what those payments are. MR. DOOLITTLE: So you have a 10 contract model much like --11 12 MR. WYND: Absolutely, yeah. 13 have, I'm sure, similar and, if not, greater contracts, because we're licensed in more 14 15 states. But one thing that was not addressed 16 was, you know, what does it cost the patient. 17 For Pentec, as a general rule, it never costs 18 the patient any more for us to go to their 19 home than it would be for them to pay a co-pay 20 in the physician's office. 21 So they're all in. So they don't have to do whatever it takes for their 22 23 caregiver to take off work, or take an 24 ambulance or whatever to get to the doctor's We do all of that for them. 25 office.

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So for a patient-specific, what
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2
    does it cost, it's no more than it would have
3
    cost in the physician's office, but -- [if]
    you ask what they would be willing to pay for
4
    it, it's substantially more, but we never ask
5
    them to pay more than what they would in the
6
    doctor's office.
7
                  MR. DOOLITTLE:
                                   The last
8
9
    question --
10
                  MR.
                      WYND:
                              Sure.
                  MR. DOOLITTLE: -- is [about]
11
12
    geography.
13
                  MR.
                      WYND:
                             Yes, sir.
                                   What are the
                  MR. DOOLITTLE:
14
    states that you would hold out as having
15
    these -- not orphan, but, you know, slightly
16
    more common than the state of Tennessee?
17
                  MR. WYND:
                             So let me address the
18
    number that is being tossed around.
19
20
    estimated that there might be two or three
    hundred patients in the marketplace on IPM's
21
                  The reality, in terms of our
22
    application.
    proprietary market research that we have done
23
   in the state, is -- it's closer to 2,000.
24
25
    There's about 1,900-plus patients that we
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referenced, in our application, that we've uncovered, via proprietary market research, are patients who have those implanted pumps in the state.

In terms of reference sources, like when the Department of Health was -- if they wanted to talk to other people that are, you know, using our model or they were using our model in their states, every state that borders Tennessee is a state that Pentec is currently licensed and doing business in, with the exception of Arkansas.

So every other state that borders Tennessee, we're doing it. We have gone through the surveys, and the next step in the process is to get a license, and then their whole policies and procedures get investigated and looked through, sifted through. And we have been approved in every other state that borders Tennessee. And I hope that is a good reference point for you.

MR. DOOLITTLE: And what about

MR. DOOLITTLE: And what about states that you're not even seeking business? In other words, they mentioned New York, and, you know, Chicago; the state of Illinois. I

mean, with regard to Pentec, are those states 1 where this is a more common procedure? 2 MR. WYND: Correct. And it's 3 very interesting. I live in St. Louis myself. 4 In St. Louis, even though we have two major 5 medical centers there, in neither medical 6 center, with their interventional pain 7 management fellowships, do they use the pumps. 8 9 They don't -- they don't do it. And it may be that it's more like what the commissioner's 10 comments were on line 8 of his comment; that 11 the therapy might -- you know, it is still in 12 13 question. In other parts of the country, it 14 is more readily used. So it varies. And sometimes the 15 place is where you would not really suspect, 16 17 because it's not necessarily geographically based where there's a high density in 18 population. But it's more so where the 19 physician -- where he or she trained, and what 20 21 he or she brings back to the community, and their passion for getting patients off of 22 these, you know, high doses of oral products, 23 who tend to create great toxicity, and implant 24 a pump which could then reduce the toxicity 25

1	and give better outcomes for the patient.
2	MR. DOOLITTLE: Thank you very
<i>'</i> 3	much.
4	MR. WYND: Certainly.
5	MR. JOHNSON: Other questions?
6	Ms. Jordan.
7	MS. JORDAN: This is for the
8	Department of Health. In the opening
9	comments, you mentioned the concern about the
10	unintended consequences of providing these
11	services in the home. Have we adequately
12	addressed that? Is that basically the concern
13	about how these drugs are dispensed, if
14	they're dispensed to the nurses or directly to
15	the patient, or are there other concerns that
16	the Department of Health has?
17	MS. BAYLES: Julia Bayles,
18	[with] Health Planning. The unintended
19	consequences is very much based in the article
20	from the American College of Occupational and
21	Environmental Medicine. That is an
22	association that Dr. Dreyzehner is a fellow
23	of, and that is an article that he found
24	helpful as a reference point. As it seems
25	based on comments from the applicants, there

1 seems to be, you know, certain doctors [who] are more likely to pursue this service in the 2 home, but we did have information from at 3 least one doctor in Tennessee who does 4 intrathecal pump services who was not 5 interested in the home health intrathecal 6 7 model. So there are certainly diversion 8 9 concerns, whether it's to the nurse, or 10 directly to the patient, or -- I mean, 11 diversion is a problem with these types of 12 these opiates and very dangerous medications, no matter what, but there are also safety 13 considerations, and quality considerations, 14 and those sorts of questions, [that] are 15 difficult to control if they're in the home. 16 So that's another really 17 important aspect of it, and that's kind of 18 encapsulated in that quote from the article as 19 The article specifically -- I mean, it 20 well. talks about the costs and the invasiveness of 21 22 the therapy and other adverse effects. So it is about diversion, but 23 24 it's also about those safety and quality issues, and it's this, kind of, big picture of 25

concerns. And it looks like Andrea Huddleston
would also like to comment.
MS. HUDDLESTON: Andrea
Huddleston, from the Department of Health.
And also just to mention the concern raised by
Mr. Elrod, we were also concerned about the
fragmentation of care here. And this is not
particularly on point, but given that we don't
have a lot of information about the number of
physicians that would be willing to refer to
this kind of service, and given that we I'm
not sure how much information we have about
accurate information that we have about the
number of pumps being used in Tennessee, the
number of physicians who implant those pumps,
the number of physicians who have really
excellent knowledge about those pumps and
their ability to service them on their own in
their office, much less having this done at
home where the physician is not able to
exercise that level of supervision.
So, again, that sort of
fragmentation, I think, we were also concerned
about that as well.
MS. JORDAN: Okay. One

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1
    follow-up:
                I think I probably know the answer
    to this, but, obviously, there is a lot of
2
    well-founded concern about compounding --
3
    compounded medications. Does the Department
4
    of Health have any idea where the medications
5
    are coming from now that these doctors who use
6
7
    these pumps -- where they're obtaining these
    compounded drugs?
                       Do we have any idea?
8
                                   I don't know
9
                  MS. HUDDLESTON:
    that we have an ability to find out that
10
11
    information.
                  MS. JORDAN:
                               I didn't think you
12
    did, but I just wanted to ask. Thank you.
13
                                   And, also, back
                  MS. HUDDLESTON:
14
    to your original question, we had talked
15
    earlier, I think, about the training for the
16
    nursing who will be engaging in this activity.
17
                                               I
18
    There's been some discussion about that.
19
    believe the application -- the IPM
    application -- acknowledged that this is very
20
    technical, very invasive, and requires an
21
    excellent skilled base. And given that there
22
23
    are not formal training programs, currently,
24
    that's part of the concern for this to be
25
    particularly done in a home health
```

	7
1	environment.
2	MR. JOHNSON: Other questions?
3	(None noted.)
4	MR. JOHNSON: Other questions.
5	(None noted.)
6	MR. JOHNSON: Well, seeing none,
7	it's time for summation. Mr. Elrod? First of
8	all, [it's] three minutes max, and we need to
9	stick to that because of the timing. And you
10	are to do or your designate is to do
11	application number two first and then the
12	first application.
13	MR. ELROD: Okay. So let me
14	just excuse me. Do I do both summations
15	now?
16	MR. JOHNSON: You can do them
17	both at the same time or separately.
18	MR. ELROD: Perfect.
19	MR. JOHNSON: Either way.
20	MR. ELROD: Both at the same
21	time. And I'm Dan Elrod, on behalf of NHC
22	HomeCare, and I appreciate the Agency's close
23	attention to this. And I really think that
24	the volume of questions that have been asked
25	really kind of make our point. And there are
	W .

so many questions about this, including a number of which that are unanswered, as demonstrated by the exchange between the Department of Health and Ms. Jordan, that that, by itself, justifies -- well, it fails to justify approval, and so it would thus justify denial.

Going back also to Ms. Jordan's questions, she asked about why couldn't they come up with physicians who would somehow quantify what we're talking about. And as I indicated earlier, the Pentec application, on

indicated earlier, the Pentec application, on page 81, lists five physician groups that they talked to; four neurology groups and one other group of physicians in Knoxville, Memphis, and Chattanooga. And none of those physicians produced any letters to quantify patients, or say "We have a need for this," or "We want the

home health model," even though they've been in touch with them.

Both of these are extensions of compounding pharmacies who have an incentive to, you know, really sell as many of their -- as much of their product as they can. There's nothing wrong with that, but I think the

1 Agency needs to understand the kind of -- what 2 underlies this model.

17.

You know, IPM says they're gonna -- that they would use an in-state compounding pharmacy, but based on the questions by Ms. Jordan about where the doctors are getting their drugs now, I don't think there's any way for the Department of Health to actually police that condition, if it were there. And so, you know, that -- I'm not suggesting that they would deceive the Agency. I'm just saying, after it -- if it were approved, there would be no way to really know that for sure going forward.

Both result in fragmentation of care. And, you know, IPM says, Oh, they will be happy to work with home health, but they have, heretofore, not been made any outreach to home health, and as far as we know, they haven't been in contact with NHC which operates statewide. They haven't indicated they've had any conversation with any other home health agency about how they would coordinate care. And, in fact, they say repeatedly in the application and otherwise,

"We focus on the intrathecal pump, and that's 1 2 it." If the need emerges for this in 3 a home setting, in a home care model -- if the 4 5 physician community in the state gets behind a home care model, the home health agency, which 6 7 is very -- or home health agency industry, which is very vibrant and strong in this 8 9 state, will emerge organically to address that And that's the way this should happen, 10 need. because that's the model in which the whole 11 12 patient would be taken care of and not just a 13 very narrow focus. 14 And so for all those reasons, we 15 would encourage the Agency to deny both of these applications. Thank you. 16 17 MR. JOHNSON: Okay. Thank you. Mr. Wynd, you're up; a maximum 18 19 of three minutes. 20 MR. WYND: Yes, sir. Doug Wynd, 21 with Pentec Health. And I'll just summarize 22 it this way: I hope you've heard that there 23 is a need for this service in this state. Again, there's about 2,000 patients who have 24 these pumps. We're forecasting that there's 25

about 40 patients that will end on service 1 2 with us at the end of our first year. 3 patients may not sound like a whole lot to a 4 lot of people in the room, but those 40 5 patients matter, and the impact that we can have on any and every one of those individual 6 7 40 patients in that first year will be dramatic. And if they were here to stand up 8 9 and tell you that, they would urge you to 10 allow us to come see them in their home. 11 Our training for our nurses is 12 second to none. If it's a 90-day training 13 program, a lot of nurses don't make it out, 14 but at the end of the day, when they get 15 through that ANCC-accredited training program, 16 our nurses know their stuff, and it's a 17 tremendously valuable service to provide to 18 the patients. 19 Our pharmacy, again, is a 20 closed-loop system, in terms of risk for 21 diversion. And all of our policies and 22 procedures -- I'm sure those would be 23 investigated if we move through the CON 24 process and go to the licensing stage, and 25 when we go through our surveys, you-guys --

I'm sure the State will look at all of our policies and procedures, and they'll be satisfied, like all of the other states that we're in, about the way we control diversion and risk of diversion for the patients.

And, lastly, in terms of orderly development of health care, for broader access to health care for patients, I'll go back to what I said in my initial comments about the way that we view the patient market. We're not gonna carve out your TennCare patients. We're not gonna carve out the Medicare patients.

Our book of business across the country are in markets in which both companies compete, but just my business selective -- or my business solely, about half of my patients I don't get fully reimbursed on. And that's something that we will do here in Tennessee, and I think that, you know, contributes to the orderly development of health care to these patients who, right now, have to go to -- [from] wherever they live or wherever they reside, however they need to get there -- to their physician to get refilled.

And we would love for the 1 2 opportunity to come here, with the appropriate 3 regulatory approval, to be here in the state to service the patients here in Tennessee. 4 5 thanks for your consideration and thanks for 6 your patience, all of y'all. 7 MR. JOHNSON: Ms. Hess? 8 MR. PUTRINO: Roy Putrino, to 9 address some of the issues from the Board of 10 Probably the majority of the drugs Health. 11 are from Florida. That's where we see that 12 they come from. I am not familiar if there 13 are any compounding pharmacies that provide this service in Tennessee. 14 15 Also, as far as the article 16 goes, they have one article. I could probably 17 bring you at least five that show the 18 significant importance of having this therapy. 19 I don't want to leave without 20 telling you the importance of the nursing 21 network across the country. If you use, as 22 this gentleman here has said, a local 23 community physician to handle the patients, 24 what happens there is that when that -- that 25 patient is trapped now in that area.

1 can't leave that area, because this is a
2 continuous infusion.

1.8

In addition, if that physician goes on vacation, what are they to do?

What's -- the hospital is not going to be able to handle it. That's why this network works so well. That's why it's great to have these nurses trained through the whole -- throughout the country.

And there were a lot of problems, and those companies are gone. And that's where you see those problems; that's where you see the pocket-fills; that's where you see the wrong drugs given. And the Corams and the Walgreens and the Aprias are all gone. They all have left this field. There's only a few of us left, and the few that are here are doing a great job. And we -- you'll see those values start to increase.

And, basically, you know, the big issue here now is patient care. And, again, I don't want you to think it's fragmented. It's actually coordinated far better than it would have been. These patients normally would stay at home and not

They would say, I can't go to 1 sav anvthing. 2 the doctor's office, so I'm not gonna do it. But, meanwhile, if they know they can get to 3 the monitoring center and they can get that 4 5 information, they can get that problem coordinated. And that's what we do. 6 7 you very much. MR. JOHNSON: 8 Thank you. 9 Discussion by the members? Dr. Fleming, and 10 then Ms. Burns. 11 DR. FLEMING: I'm sorry. Ι 12 can't hesitate to at least insert that, from a 13 physician's perspective and from a patient 14 advocacy perspective, there's a small group of 15 patients who are in desperate need for help. 16 Chronic pain is one paramount in the national 17 health organizations in the country now as a 18 It's the fourth vital sign. I mean, so need. 19 pain management is not a small deal, and for 20 folks in chronic pain, this opportunity could 21 be life-changing. 22 I'm not a pharmacy regulatory 23 person -- and this is not a legal statement --24 but from a physician's perspective, I can 25 guarantee that there are patients that would

1 benefit from this concept, and I am an 2 advocate for them. 3 MR. JOHNSON: Ms. Burns. 4 MS. BURNS: I'm honestly having 5 a hard time with this application. I really 6 don't think we have enough information. 7 that's not to say we didn't have tons of paper to review, but it would have been really nice 8 9 if the applicants had provided information from the states where this is going on, or if 10 11 they could have had a doctor come in and talk 12 to us, or if they could have provided, you 13 know, information from those physicians. 14 could have been really nice if the Department 15 of Health had gone out and talked to other 16 states to have more information for us. 17 I'm just having a really hard 18 time knowing, you know, what we need to do. 19 Is it right for the patient? Probably, it is. 20 Do our home health agencies need to be doing 21 this? Probably not. As a nurse, I cannot 22 imagine being a home health nurse and only 23 doing this two or three times a -- you know, I 24 mean, once every two or months. My competency 25 level would not be there, and it would

probably be of more harm to the patient than good for them.

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So I'm really having a hard time with this application, not knowing if we really have enough information to really make an informed decision.

MR. JOHNSON: Mr. Doolittle.

MR. DOOLITTLE: I'd like to echo Ms. Burns' concerns. What bothers me the most -- and I inherently think that this is probably a good service that ought to be licensed in the state, but it does strike me that the Department of Health does not have nearly enough information to get comfortable with it, and also to see, most particularly, where it is being done successfully in other states in volume, what the pros and cons are, and what are the things to look out for.

And so I really do think that it is tough for us to license a new service which is only being performed, apparently, by physicians on a home health basis, without having the overall regulatory authority in the state feel comfortable that when it goes into service, it's going into service in the

1 correct manner. And we can learn from other 2 state's mistakes. Thank you. MR. JOHNSON: Other discussion 3 4 by the members? Mr. Wright. MR. WRIGHT: 5 And I think I would just add to that: On a scale of 95 counties, 6 7 it would be problematic with the information 8 we have. 9 MR. JOHNSON: I'll just make one comment. I think Ms. Jordan brought it up 10 11 originally and others had amplified the need That's not well-defined. We don't 12 question. 13 really know. Usually in these kinds of things, there's an outcry publicly before we 14 15 ever see it and before, perhaps, the 16 Department of Health would see it. And there may be an outcry, but if it is, it's hidden. 17 18 And I think that gets back to the lack of 19 information that we have. And so I too am 20 conflicted. 21 I understand as a consumer rep that patients do need this service, and some 22 are probably not capable of getting to 23 24 doctors' offices regularly. And they're the 25 ones that need the help the most. The others

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can make it and it works for them. They're						
getting help now. It may not be convenient						
for them. Also, I think the cost numbers have						
been all over the board.						
As we get into this, we have						
some options in terms of what we do as an						
agency. And this is part of the discussion,						
so I just want to sort of lay it out; what our						
opportunities are. We could approve one, two;						
one or two of the applications. We can deny						
both or one. Or the one we haven't ever						
discussed, as far as I'm concerned, is we can						
defer this until we get more information.						
I think that would						
Mr. Counsel, is that a legitimate motion, if						
we choose to do that?						
MR. CHRISTOFFERSEN: It can be						
done.						
MR. JOHNSON: Pardon?						
MR. CHRISTOFFERSEN: It can be						
deferred for or they can be deferred for up						
to 90 days.						
MR. JOHNSON: For how many?						
MR. CHRISTOFFERSEN: Up to 90						
days.						

1 MR. JOHNSON: Thank you. 2 those are our options, as I see it. And at 3 this point, I haven't seen anything that would 4 convince me to vote for either applicant right 5 There are a few things that would now. 6 convince me to vote against it, just because 7 of the lack of information. However, I don't want to -- I don't feel like I would want to 8 9 decline a service that's needed because I'm 10 reluctant to get the information to make it 11 possible. 12 So those are our options, as we 13 go forward. So further discussion by the members? Mr. Wright, and then Mr. Gaither. 14 15 MR. WRIGHT: Mr. Chairman, the 16 other thing I'd like to add: The need is not something I struggle with as much as I do with 17 18 the lack of information that helps me make a 19 determination about the orderly development. 20 I think that's my biggest concern. 21 MR. JOHNSON: Mr. Gaither. 22 This is for legal MR. GAITHER: 23 So if we defer, are they allowed to counsel. 24 present -- how does that work? Does everybody 25 get to present more information, or does the

1 application stand on its own and you ask 2 I'm just trying to understand. questions? 3 Because the need would have to be addressed with additional information, not just more 4 input from the Department. That's got to be 5 6 some additional paper or something? 7 MR. CHRISTOFFERSEN: If this 8 were to be -- or if one or both of these -- I 9 assume both -- were to be deferred for a 10 period of time, there wouldn't be any point in 11 doing it without looking at new information; 12 therefore, I would expect that the applicants 13 and the opposition and the Department of 14 Health and Agency staff would all have the 15 opportunity to explore some of the questions 16 raised by the Agency. 17 As a matter of fact, the more 18 quidance the Agency could give, if they were 19 to do it, as to exactly what they want 20 answered -- though I think if that evidence 21 had been clear anyway, it would be helpful. 22 MR. GAITHER: I think that's 23 where I was going, is we would have to tell 24 you what we really want to know on that. 25 MR. CHRISTOFFERSEN: That would

1	be helpful.							
2	MR. JOHNSON: Other discussion?							
3	(None noted.)							
4	MR. JOHNSON: Well, one further							
5	comment, that the Department addressed that we							
6	haven't talked much about, is the abuse issue.							
7	Tennessee is not the most abusive drug state							
8	in the country, but it's one of them. It's							
9	probably in the top ten. And that's a							
10	concern.							
11	MS. HILL: We're ranked two.							
12	MR. JOHNSON: We're ranked two?							
13	MS. HILL: I think so.							
14	MR. JOHNSON: Okay. So it is a							
15	concern and a big concern. And I don't see							
16	unless we're able to regulate this situation							
17	in a reasonable way, I don't see that getting							
18	any better because of what we might do. So I							
19	think that needs to be addressed too, if we							
20	should agree to defer.							
21	Ms. Austin?							
22	MS. AUSTIN: I guess it's just							
23	my understanding that we've already deferred							
24	these applications once for extensive							
25	questions by the Department of Health and by							

1	the HSDA staff. I'm just not sure and they						
2	weren't able to provide, still, the						
3	information that was outstanding. I just						
4	don't know how much more they're gonna be able						
5	to give us at this point.						
6	MR. JOHNSON: Well, I don't know						
7	either, but I suspect that they probably have						
8	a better direction of what questions the						
9	Agency has after today than they had before we						
10	talked about it. So it seems to me the						
11	questions are pretty specific now. Probably						
12	less than five or so big theme-type questions						
13	that need to be answered. And I think the						
1,4	minutes will show what those are, and we can						
15	summarize those.						
16	Other discussion?						
17	(None noted.)						
18	MR. JOHNSON: Well, if there is						
19	none, a motion is in order to do one of three						
20	things. We can one, two, defer, neither						
21	and/or approve neither. So those are our						
22	options. So a motion is in order.						
23	MS. HILL: For Implanted Pump						
24	Management first.						
25	MR. JOHNSON: Pardon?						
	ı						

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1	MS. HILL: IPM is the first one.						
2	MR. JOHNSON: Oh, I'm sorry. I						
3	need to say that we need to deal with these						
4	separately, not collectively. So we'll deal						
5	with Implanted Pump Management first, and then						
6	we will do Pentec separately.						
7	So a motion is in order.						
8	MR. DOOLITTLE: May I ask						
9	MR. JOHNSON: Mr. Doolittle.						
10	MR. DOOLITTLE: I have a						
11	question of the chairman. I think it's only						
12	fair that we try to delineate exactly what						
13	we're looking for. Is it possible for us to						
14	supplementally deliver a letter to the						
15	applicants and say: We've got the following						
16	five areas that we'd like and the						
17	Department of Health five areas we'd like						
18	you to elaborate on? Is that possible, or do						
19	we have to invent this right now?						
20	MR. JOHNSON: Ms. Hill?						
21	MS. HILL: Certainly,						
22	Mr. Doolittle. If your decision is to defer						
23	the application, then it certainly would be						
24	appropriate to delineate the information that						
25	you are looking [for] from them; otherwise,						

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1
    you would be, you know, voting to approve or
 2
    deny something.
 3
                  MR. DOOLITTLE:
                                   Okay.
                                          Well,
    that's my question. Can we supply it, you
 4
 5
    know, in writing supplementally?
 6
                  MR. JOHNSON: Mr. Christoffersen,
 7
    do you have additional -- you looked like you
 8
    were about to answer.
 9
                  MR. CHRISTOFFERSEN:
                                        Yes.
10
                  MR. JOHNSON: Other questions or
11
    discussion?
12
                   (None noted.)
                                 A motion is in
13
                  MR. JOHNSON:
14
    order for Applicant No. 1, which is Implant
15
    [Pump] Management. Mr. Doolittle.
16
                  MR. DOOLITTLE:
                                   Regarding
17
    Implant Pump Management, CN1407-027, I move
18
    that we defer this application for up to 90
19
    days to solicit additional information on
20
    specific subjects to be transmitted to the
21
    applicant in writing within the next week, and
22
    the same set of questions for possible
23
    additional information be transmitted to the
24
    Department of Health for additional research
25
    on their part.
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1	MR. JOHNSON: That's a proper	
2	motion. Is there a second?	
3	MS. BURNS: Second.	
4	MR. JOHNSON: All right.	
,5	[Seconded by] Ms. Burns. Please call the	
6	roll.	
7	MR. AUSBROOKS: Jordan?	
8	MS. JORDAN: Yes.	
9	MR. AUSBROOKS: Flora?	
10	DR. FLORA: Yes.	
11	MR. AUSBROOKS: Gaither?	
12	MR. GAITHER: Yes.	
13	MR. AUSBROOKS: Wright?	
14	MR. WRIGHT: Yes.	
15	MR. AUSBROOKS: Doolittle?	
16	MR. DOOLITTLE: Yes.	-
17	MR. AUSBROOKS: Burns?	
18	MS. BURNS: Yes.	
19	MR. AUSBROOKS: Austin?	
20	MS. AUSTIN: Yes.	
21	MR. AUSBROOKS: Fleming?	
22	DR. FLEMING: Yes.	
23	MR. AUSBROOKS: Byrd?	
24	MS. BYRD: Yes.	
25	MR. AUSBROOKS: Johnson?	
		4

1	MR. JOHNSON: Yes.							
2	MR. AUSBROOKS: Ten "yes."							
3	MR. JOHNSON: The motion passes.							
4	The application is deferred for up to 90 days.							
5	And I will ask the Department to put a time on							
6	it, based on other applications to be heard,							
7	and the timing that you think the information							
8	can be gathered. I don't think it'll be 30							
9	days, but it may not need to be 90. So we							
10	will address that question with the staff.							
11	All right, then. A motion is in							
12	order for Pentec. Mr. Doolittle.							
13	MR. DOOLITTLE: Regarding Pentec							
14	Health, Inc., CN1411-046, I make the same							
15	motion that the application be deferred for							
16	consideration for up to 90 days to allow the							
17	applicant to address a few additional requests							
18	for information and that a similar request,							
19	perhaps with additional things, be transmitted							
20	to the Department of health.							
21	MR. JOHNSON: That's a proper							
22	motion. Is there a second?							
23	MS. BURNS: Second.							
24	MR. JOHNSON: Seconded, again,							
25	by Ms. Burns. Please call the roll.							

	-					
1	MR. AUSBROOKS: Jordan?					
2	MS. JORDAN: Yes.					
3	MR. AUSBROOKS: Flora?					
4	DR. FLORA: Yes.					
5	MR. AUSBROOKS: Gaither?					
6	MR. GAITHER: Yes.					
7	MR. AUSBROOKS: Wright?					
8	MR. WRIGHT: Yes.					
9	MR. AUSBROOKS: Doolittle?					
10	MR. DOOLITTLE: Yes.					
11	MR. AUSBROOKS: Burns?					
12	MS. BURNS: Yes.					
13	MR. AUSBROOKS: Austin?					
14	MS. AUSTIN: Yes.					
15	MR. AUSBROOKS: Fleming?					
16	DR. FLEMING: Yes.					
17	MR. AUSBROOKS: Byrd?					
18	MS. BYRD: Yes.					
19	MR. AUSBROOKS: Johnson?					
20	MR. JOHNSON: Yes.					
21	MR. AUSBROOKS: Ten "yes."					
22	MR. JOHNSON: The motion passes.					
23	The application is deferred for up to 90 days,					
24	with the same stipulations about					
25	communication.					

Response to Agency Members Questions

Implanted Pump Management CN1407-027

FARRIS BOBANGO, PLC

ATTORNEYS AT LAW

Nashville · Memphis

HISTORIC CASTNER-KNOTT BUILDING 618 CHURCH STREET, SUITE 300 NASHVILLE, TENNESSEE 37219

(615) 726-1200 telephone · (615) 726-1776 facsimile

Rachel C. Nelley rnelley@farris-law.com

Direct Dial: (615) 687-4231

May 22, 2015

Ms. Melanie M. Hill Executive Director Health Services and Development Agency Andrew Jackson Building, Ninth Floor 502 Deaderick Street Nashville, TN 37243

RE: March 25, 2015 Deferral of Implanted Pump Management, LLC ("IPM") Certificate of Need Application #CN1407-027

Dear Ms. Hill:

Please allow this letter to serve to follow up the filing of the above-referenced certificate of need application and as a response to your correspondence dated April 2, 2015, wherein additional information or clarification was requested.

1. Based on the information provided by the Tennessee Department of Health, it appears implantable intrathecal pumps may not be safe. Please provide expert opinion on the safety and efficacy of the pumps.

Response: Please refer to the enclosed letter from David L. Caraway, M.D., PhD, the Medical Director at the Center for Pain Relief at St. Mary's Regional Medical Center in Huntington, West Virginia included as Attachment 1. Dr. Caraway's Curriculum Vitae and a list of his publications are also included. Additionally, an overview of intrathecal drug delivery for chronic pain literature prepared by Medtronic, pump manufacturer, is included.

2. Describe in detail the safety of refilling the pumps in the home versus a physician office. Who refills the pump in the physician office setting is it the physician or a nurse or someone else? If someone other than the physician, detail the oversight provided by the physician.

<u>Response</u>: Refilling the intrathecal pumps in the homecare setting rather than in a physician office setting provides significant safety advantages. While a physician's

office will generally designate one RN, NP or MD to be responsible for all of the pump refills prescribed for the patients of the practice, that practitioner will typically have less training in both theory and the mechanics of the intrathecal pump and less experience in comparison to the nurses refilling the intrathecal pumps in the homecare setting under the IPM model. In a physician's office, the pump refills represent only a small portion of the designated clinician's responsibilities. It would be impractical for a physician's office to engage one full time practitioner dedicated to only pump refills. Under the IPM model, the nurse refilling a patient's intrathecal pump has been engaged to provide services specifically related to intrathecal pump refills. As with many nursing and or clinical skills, proficiency comes only with experience and repetitiveness. This proficiency cannot generally be achieved in the MD office model as it can with the IPM model where the focus of training includes not only the refilling and required programming of the pumps, but also the mechanics of the system, potential red flags and education required for the patient. The greater proficiency available under the IPM model has a direct impact on improved safety because it leads to fewer mistakes in patient care. Additionally, the safety net available under the IPM Model improves patient outcomes. A physician's office typically will not have the tickler system in place or the staff and resources available to manage alarm dates and times when the pump must be refilled.

3. Address the risks associated with accessing the spinal port in the home. Provide any statistics for incidents, adverse events, or reported complications over the past 3 years and the outcomes. Both applicants have noted having a national presence in the implanted pump market so additional clarification regarding safety issues is needed.

Response: The Applicant would like to clarify that the catheter port (direct route to the CSF) is not accessed in the homecare management model. Only the reservoir port (the collapsible pump reservoir) is accessed in the homecare management model. Although there are errors that do occur in the homecare model, they are much lower compared to that of the MD office model -- less than 2% pump pocket complications.

4. Describe when the procedure is clinically contraindicated (when a refill will not be performed).

Describe in detail how the medications will be protected from theft, misuse, and/or abuse from the time the nurse receives the medication until it is delivered to the home. How will the proper use of opiates be monitored and regulated?

Have there ever been incidents of opiate abuse by employees of your company in any of the other states in which you operate? If so, please describe in detail how those were handled.

Response: The procedure is not clinically indicated and, thus, not performed, when the RN is not able to 100% successfully access the reservoir port. This might occur post-surgical intervention, if a seroma is present, or if the pump has inverted and cannot be accessed. Any time that a pump cannot safely and efficiently be accessed

the MD will be notified and IPM's RN will await further instructions from the ordering MD. It is important to note that, under IPM's model, each patient will be scheduled three to five days prior to an anticipated alarm date (i.e., the date that the pump will alarm due to low volume). IPM has a tickler/monitoring system in place so that pump refills can be scheduled and occur before the pump volume becomes too low and triggers an alarm. This advance scheduling helps to ensure that any unforeseen circumstances such as inclement weather or trouble with successful pump access do not interfere with the delivery of a patient's medication — issues can be addressed and rectified before the patient's pump begins to sound an alarm due to low volume.

The medications will be delivered to the patient's home (due to the Tennessee Department of Pharmacy stating the medication cannot be delivered by the RN) via FedEx using tamper proof packaging. The delivery will be scheduled the day before a nurse is scheduled to be present at a patient's home for a pump refill to ensure the availability of the medication for the pump refill. Additionally, medication will be shipped via a double packaging system as a matter of IPM safety policy. If there is any damage to the inside of the box (where the medication is packaged) the RN will not use that medication. The medication will be wasted and reordered from the pharmacy. IPM will also utilize tamper proof packaging for the syringe, caps that can only be opened once. This will ensure that if any tampering has occurred the RN will visualize the attempt at tampering and discard the medication. The medication delivery will also require a signature and never be left at the door. The signature confirmation will be tracked using a FedEx supplied tracking system. This tracking information will be kept by IPM for five years.

Tennessee regulators can track the proper use of opiates with the State's current dispensing tracking systems and MD prescribing habit monitoring.

Each RN employed by IPM will be subjected to a background check and a drug screen prior to employment and again at least annually. IPM also reserves the right to perform additional random drug test throughout the year. Employee participation in the drug test is mandatory and if refused the employee will be relieved of their job duties.

5. Emergency procedures were addressed in the applications, but more detail is requested. What are the emergency procedures if there is an adverse reaction during the refill procedure? After the procedure is complete and the nurse is still in the home? When nursing personnel are not in the home? After the procedure, and nursing personnel have left the home?

Response: Emergency procedures are similar to those that a physician's office has in place. The RN will call 911 and monitor the patient's vital signs and level of consciousness and perform CPR if clinically required until emergency personnel arrive. The RN will hand over clinical care to the trained emergency professionals upon their arrival and provide all pump information to the EMTs. The prescribing physician would be notified via phone of the event, as well as the emergency room that the patient was being transferred to. The RN would follow the patient in his/her own

vehicle to the appropriate ER and await any MD orders. In some instances, the MD wishes the pump to be set at minimal mode or stopped and the IPM RN would be able to do that. Most ER's or hospital systems do not have the programmer and or pump programs to perform this function. If the patient experiences any different or concerning effects in the home when a RN is not present, they have access to 24 hour on call staff through IPM and/or 911 based on the severity. The 24 hour line will triage and help to determine if emergency medical assistance is necessary. The IPM patient will also be provided with a medic alert bracelet, which in the event of emergency, provides IPM's 1-800 phone number and indicates that the patient is receiving intrathecal therapy. This service provides a quick link for emergency personnel to ascertain vital medical information quickly.

6. The patient to nurse ratio of 40 to 1 seems unrealistic, especially since both applicants sought to cover a large geographic area such as Tennessee. How many nurses would it take to provide adequate coverage in Tennessee, and from where would you hire these skilled nurses?

Response: The patient to nurse ratio would stay at 40 to 1, but 40 patients would represent a full time employee (40 hours per week). Based on demographics and the patient distribution, IPM might have to hire a part time RN in East Tennessee, and then utilize another part time RN to cover Middle Tennessee. The defining factor when looking for a RN patient distribution is the distance from the patient to the RN. IPM will use 180 miles radius as a starting point to define RN patient census.

7. During the March 25, 2015 Agency meeting, Mr. Doug Wynd, Pentec National Sales Director of Specialty Infusion, stated there were approximately 80,000 individuals with implanted intrathecal pumps in the U.S, including 75,000 receiving ongoing care from their physicians and 5,000 receiving care in their homes from licensed home health agency nursing staff under physician orders. Mr. Wynd noted Pentec was serving approximately 2,800 of the 5,000 in the home setting (draft transcript, pages 37 and 53). Due to the wide variation in estimates of implanted pumps in Tennessee (I PM used 300 Medtronic implanted pumps while Pentec estimated approximately 1,730 total pumps) please clarify the difference in the two estimates, and document the basis for the estimates.

Please identify the number and source(s) of patients that are presently being treated in a physician's office in Tennessee. Are any physicians expected to stop providing this service in the office if a home health option becomes available?

Response: IPM's 300 pump patients figure as set forth in its application is based on a manufacturer representative's estimate. Following the March 25, 2015 meeting of the Agency, IPM contacted Medtronic, the lead manufacturer of intrathecal pumps in the United States. The company reported to IPM that for the CY14- CY15, 621 pumps were sold to facilities in Tennessee. From 1/1/14 to 4/23/15, 595 pumps were implanted in the state of Tennessee. Medtronic has specifically requested that IPM indicate that the number of pumps will be only from one of the three pump manufacturers. Although the actual number of individuals with intrathecal pumps in

the state of Tennessee is estimated to be at least three times higher based on one manufacturer's data, the actual number of individuals who might benefit from a homecare management program is estimated to be in the thousands.

8. Please provide testimony (in person or by letter) from physicians with practices in each Grand Division of Tennessee (East, Middle, and West) who would support this specialty service in the home, including the approximate numbers of patients needing this service. Provide sufficient letters to support the service area requested.

Provide letters of support from patients in each Grand Division of Tennessee not being treated due to not being able to travel to a physician's office as well as from patients who would find this home option more convenient. Provide sufficient letters to support the service area requested.

Response: IPM sent questionnaires to various pain management practices across the State. The responses from all of the practitioners indicated that they would use a homecare management service to assist in refilling, programming and titrating intrathecal pump if one was available. Included as Attachment 8 are copies of responses received from practitioners in Hendersonville, Murfreesboro and Hermitage (as representative of Middle Tennessee), from Cordova (as representative of West Tennessee) and from Kingsport (as representative of East Tennessee). IPM did not have access to patients and, thus, did not obtain these requested letters of support.

9. How often does a physician have to see the patient before these medications can be refilled?

Response: The frequency of the physician visits required for patients is based on MD preference and State guidelines. If the individual does not require any oral pain medications, the frequency will be lower than that individual who requires oral pain medications in adjunct with the intrathecal pump. The most common approach to intrathecal pain management is to develop with the patient the overall goal of elimination and/or a great reduction in any oral pain medications. This approach will lead to a less frequent need to visit the MD offices in the event that the patient is receiving homecare services in regards to the intrathecal pump. In short, the frequency can range from every three months, to twice a year. More frequent visits would be required if oral narcotics are still being prescribed by the MD.

10. What is the current estimated cost and payor reimbursement by major CPT codes pertaining to intrathecal implanted pump refill visits in physician offices in TN? How does this compare to your cost and reimbursement?

IPM projects an average gross charge of \$200/visit while Pentec identified \$2,517/visit. Although total gross revenue of both applicants is very close in Year 1 (approximately \$300K), the difference in projected patient visits results in a wide variance in the projected average gross charge. Please identify the key components of your rate structure with related CPT codes used to bill for implanted pump refills in physician offices, home health, and pharmacy settings. Note: For purposes of comparison, it is

suggested the key components of the proposed rate structure identified in the Pentec application be used in the response for this question. Specifically, the rate would include the charges by four basic categories - medications, supplies/materials, nursing time and a per diem that covers allocated corporate support costs, such as IT, billing, etc. (transcript, Pentec presentation, page 54-55).

Response: IPM's structure differs from that of Pentec. IPM is solely a nursing entity that subcontracts for pharmacy services. IPM will only be able to bill the nursing visit at \$200/visit. The subcontracting pharmacy will bill for the medication and also for any applicable rate allowed by contract standards. The per-diem rate that Pentec refers to is a subcontracted service from IPM. The subcontracted pharmacy BHI, Ohio Compounding, or local Tennessee pharmacies selected will be able to bill for the indicated per-diem code.

11. Provide comprehensive state regulations for each state in which you operate this type program.

How are these agencies regulated by each state, as home health agencies or pharmacies or as some other type entity? Disclose and discuss any sanctions of existing licenses in other states in which you operate this type program and provide evidence that your company is in good standing.

Have you ever been denied a certificate of need or a license (home health or pharmacy) in any state? If so, please provide documentation such as staff reports, minutes, denial letters, and/or transcripts.

Response: Please note that, in response to a request from IPM, on May 8, 2015, HSDA's Executive Director modified the request for "comprehensive state regulations for each state" as follows:

Please provide a summary of the applicable requirements in each state in which you operate intrathecal pumps in the home health environment with supporting documentation as needed. Please note whether there are specific CON standards, nurse education requirements related to intrathecal pumps, or drug transport requirements, or any other special requirements related to those states.

Implanted Pump Management ("IPM"), a New Jersey limited liability company, is currently licensed in Florida, Utah, Kentucky, Virginia and Texas to provide the specialized skilled nursing services associated with refilling, programming and titrating intrathecal pumps in the home for patients. IPM has a pending application for licensure in Colorado. The provision of a single type of home infusion is exempt from home care licensure in the following states: Alabama, Alaska, Arkansas, Connecticut, Delaware, Georgia, Idaho, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, new Jersey, North Dakota, Ohio, Oregon, Pennsylvania, South Dakota, Vermont, Washington, West Virginia, Wisconsin, and Wyoming.

IPM has not been denied a CON. While Florida, Kentucky and Virginia have certificate of need (CON) programs in effect, only Kentucky requires a CON for the services provided by IPM. Kentucky granted IPM a CON on November 26, 2014 to establish a "mobile health service" to provide intrathecal home management in all Kentucky counties except Fayette, Laurel, Knox and Whitley. A copy of Kentucky's laws relative to mobile health services is included as <u>Attachment 11</u>. Summaries of each state's CON programs and summaries of the facilities and services regulated by CON laws in each state are available at the National Conference of State Legislatures ("NCSL") website at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#Regulated

Information about pharmacy and prescription drug regulations in all states is available at the NCSL website in its 2015 State Legislative Database http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx. No laws pertaining exclusively to intrathecal pumps were found.

IPM is wholly owned by Mr. Putrino and managed by him as the company president. Mr. Putrino also owns a 70% interest in Basic Home Infusion ("BHI"), a Joint Commission Accredited Specialty Infusion pharmacy located in New Jersey which provides only medications required for the management of surgically implanted intrathecal pumps. BHI is licensed in 42 states, but does not provide pharmacy services in all of these states. In Kentucky, BHI contracts with IPM to provide intrathecal homecare management services.

A table summarizing the licenses held by BHI and IPM in various states is included as <u>Attachment 11</u> along with documentation of good standing.

12. Did either applicant consider contracting with existing home health agencies to provide this service? If not, please explain why. In a contractual situation, the services could be provided under an existing agency's license utilizing IPM or Pentec nurses to provide the service. Discuss the pros and cons of this scenario and how reimbursement would differ.

Response: Subcontracting with an existing licensed home health agency in the state of Tennessee presents safety concerns similar to those described relative to a private physician's office in response to question 2. Given the complex nature of the therapy, a concentrated, sole focus on the therapy is the only pathway that leads to the highest success rates in patient care. The traditional home health registered nurse does not have the necessary proficiency from experience and training because he/she cannot focus solely on implanted intrathecal pumps. The greater proficiency available under the IPM model has a direct impact on improved safety because it leads to fewer mistakes in patient care. Notably, at the meeting on March 25, 2015, the home health agency that opposed IPM's application, admitted to the agency members that it was not "able to perform the therapy."

13. Should the Agency determine there is a need for this type specialty home health agency, would the applicants be willing to consider approval for only half of the service area requested so that two agencies would cover the state instead of just one? Would the project still be financially feasible if only a portion of the service area were approved?

Response: Should HSDA determine that there is a need for the proposed specialized services, IPM would not concede to approval of only half of the state so that the other half of the State could be served by Pentec. The reason that IPM considers this an un-safe option is that there is documented proof that Pentec still has an ongoing investigation with the FDA that illustrates unsafe pharmacy conditions. The findings on the FDA report of Pentec certainly show similarities to those of the NECC FDA findings. IPM does not support the introduction of the proposed services by any company that does not maintain exemplary standards and care in regards to intrathecal home management.

14. The final question is for Implanted Pump Management. In the application and during testimony on March 25, 2015, Mr. Putrino indicated his infusion pharmacy company, Basic Home Infusion, had licensed pharmacies in 14 states and that IPM would be operating home health agencies in three states-Florida, Utah, and New Jersey. Mr. Putrino is quoted on page 16 of the attached transcript as saying "This model has allowed us to grow to a national level via word of mouth, and it is our desire to bring this model to Tennessee" and on page 95 as saying "Let's take this regional contract and make it national." Please explain these comments about going national with only three not yet operational home health agencies. Is IPM or its sister infusion pharmacy company providing direct hands-on skilled nursing services in other states directly to patients via contracts with individual nurses or in some other manner?

Response:

Let me begin by clarifying what the transcript actually says: (Page 16, lines 2 and 3) "As a Pharmacist, I am licensed in 14 states" A "Pharmacist license" is issued to an individual. Some States, like Tennessee, requires that in order for a facility to be eligible for an Out of State Pharmacy license, the "Pharmacist of Record" must pass a Pharmacy Law exam and become a licensed Pharmacist in that state. This statement was made to indicate that as the owner I take full responsibility for knowing the law of each state, as they all differ. A "Pharmacy License" on the other hand, is issued to a physical pharmacy and only when the facility has met or exceeded the requirements set forth by each "Board of Pharmacy". BHI currently is licensed in 45 states for Intrathecal therapy.

As to the actual question, BHI is the sister company of IPM and currently, holds the rest of the licenses to provide RN services in the other states. IPM was recently established, with the guidance of the Joint Commission, to better conform to each state's nursing regulations and streamline the process. Having a Pharmacy apply for a CON is like putting a round peg into a square hole. Since both entities have different responsibilities the

policies and procedures are often quite different. Even the surveys are focused on different aspects, so a pharmacy may only be accredited for the pharmacy portion and not have any accreditation in the nursing area. In addition, the financial crossover adds confusion as costs associated with nursing are often melted into the pharmacy costs, which is often misleading.

Since the establishment of a separate company for nursing, our organization has been able to better respond to both the application process and the ongoing communication between each "Board of Nursing".

Should you have any questions or require additional information pertaining to this application, please do not hesitate to contact me by telephone at 615.726.1200 or by e-mail at rnelley@farris-law.com.

Sincerely,

Rachel C. Nelley

Enclosures

cc: Melissa Hess, Implanted Pump Management

AFFIDAVIT

STATE OF TENNESSEE				
COUNTY OF PASSAIC				
NAME OF FACILITY: Implanted Pump Management LLC				
I, Mekse Hess, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.				
Melins Kin & D.d. U. Signature/Title				
Sworn to and subscribed before me, a Notary Public, this the 21 st day of MAY, 2015, witness my hand at office in the County of PASSAIC, State of Tennessee.				
NOTARY PUBLIC				
My commission expires APRIL 16 Th , 2020 . BRYNN BEEKMAN NOTARY PUBLIC OF NEW JERSEY My Commission Expires 4/16/2020				
HF-0043				

Revised 7/02

AFFIDAVIT

STATE OF TENNESSEE
COUNTY OF PASSAIC
NAME OF FACILITY: IMPLANTED PUMP MANAGEMENT LLC
I,, after first being duly sworn, state under oath that I am the
applicant named in this Certificate of Need application or the lawful agent thereof, that I
have reviewed all of the supplemental information submitted herewith, and that it is true,
accurate, and complete.
Signature/Title
Sworn to and subscribed before me, a Notary Public, this the 19th day of MAY, 2015,
witness my hand at office in the County of PASSALC , State of Tennessee.
NOTARY PUBLIC
My commission expires APRIL 16 TO BRYNN BEEKMAN NOTARY PUBLIC OF NEW JERSEY
HF-0043 My Commission Expires 4/16/2020
Revised 7/02



To whom it may concern:

I am writing as a practicing physician and researcher in the field of intrathecal drug delivery ("IT pumps"). I have practiced in the neighboring states of West Virginia, Ohio and Kentucky for 20 years and have published extensively in peer-reviewed journals regarding this therapy and I am a frequent lecturer to medical societies both nationally and internationally.

IT pumps are a drug delivery device that allows full physician control of dosing. There is little potential for diversion, abuse or self-administered overdose. Thus, in our region where pain pill abuse and diversion is rampant, the opportunity to treat patients with severe chronic pain without oral oploids by providing access to this vital therapy is without question a needed service.

Furthermore, intrathecal drug delivery provides analgesia with much reduced side effects such as constipation, nausea and somnolence. The same device is used with baclofen to treat neurological symptoms such as severe spasticity due to spinal cord injury or multiple scierosis. High level evidence supports the use of IT pumps in pediatric cases for cerebral palsy.

Recently, I transferred the intrathecal pump management of more than 200 patients from my office to a home care management company. Under my strict prescriptive authority the actual refilling and programming of the device is accomplished at the patient's home or institution. This has been and incredible advantage to these patients. In some cases, rather than taking long ambulance rides with all of the associated costs and inconvenience these health care providers are able to provide safe and convenient management of this important treatment.

In-home management has been praised almost uniformly by my patients who choose to use this service. Physicians also benefit by having care provided by dedicated nurses with extensive experience and training and whose exclusive duties are safe pump management.

I am happy to provide further information or literature references if desired. In fact, I have a publication in press that reviews outcomes of 100 consecutive IT pump patients who have been completely taken off oral opioids with improved pain control, reduced side effects and improved safety.

Thank you for taking the time to review this strong recommendation to continue to support IT pump therapy and to introduce intrathecal homecare management into the state of Tennessee.

Sincerely,

Bavid L. Caraway, MD, PhD

Medical Director

Center for Pain Relief at St. Mary's Regional Medical Center, Huntington, WV.

David L. Caraway, MD, PhD

Recent Peer-reviewed Publications

- Hatheway, J. A., Caraway, D., David, G., Gunnarsson, C., Hinnenthal, J., Ernst, A. R. and Saulino, M. (2015), Systemic Opioid Elimination After Implantation of an Intrathecal Drug Delivery System Significantly Reduced Health-Care Expenditures. Neuromodulation: Technology at the Neural Interface. doi: 10.1111/ner.12278
- Caraway, D., Hunter, C.: "Commercially Available Reservoir Options for Intrathecal Pump Delivery" Chapter 63; Diwan/Staats' Atlas of Pain Management Procedures; McGraw Hill, New York Atlas of Pain Medicine Procedures. November 25, 2014
- Saulino M, Caraway D et al: The PRIZM (Patient Registry of Intrathecal Ziconotide Management) Study for Patients With Severe Chronic Pain. Neurology April 8, 2014 vol. 82 no. 10
- 4. Timothy R Deer, David L Caraway, Mark S Wallace: A definition of refractory pain to help determine suitability for device implantation. Neuromodulation 2014 Dec;17(8):711-5
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DAVID L. CARAWAY, M.D., Ph.D.

510 Bell Farms Lane Palmyra, VA 22963

1816 Lexington Avenue Ashland, KY 41101

CONTACT:

Carawaymd@aol.com

Caraway@nevro.com

Personal Mobile: 434.882.1790 International Mobile: 650.400.9101

MEDICAL OFFICE:

St. Mary's Regional Medical Center

Pain Relief Center 2900 First Avenue Huntington, WV 25702

(304) 526-8390

BUSINESS:

Nevro Corporation

4040 Campbell Avenue, Suite 210

Menlo Park CA 94025

Executive Administrator: Laura L Hoedl

Hoedl@nevro.com Direct - 650-433-3235

EDUCATION:

M.D. - May 1992

University of Virginia School of Medicine

Charlottesville, Virginia 22908

Ph.D. in Biophysics - May, 1991

University of Virginia, Graduate School of Arts and Sciences

Charlottesville, Virginia 22908

Medical Scientist Training Program - 1986 - 1992. Merit based

scholarship funded by the National Institutes of Health

B.S.Ch.E. with highest distinction in Chemical Engineering

May 1986

University of Virginia School of Engineering

Charlottesville, VA 22908

POST-GRADUATE TRAINING:

1995 - 1996, Subspecialty Training:

Additional training in Pain Management

Pain Management Center, University of Virginia

HCS Box 238

Charlottesville, VA 22908

1993 - 1996, Anesthesiology Residency University of Virginia School of Medicine

Charlottesville, VA 22908

1992 - 1993, Internship (Internal Medicine) University of Virginia School of Medicine Department of Anesthesiology Charlottesville, VA 22908

PRACTICE HISTORY:

Pain Management-

1996 - 1998: Centers for Pain Relief. Opened, developed and managed five multidisciplinary interventional pain management centers in West Virginia. Responsible for delivery of medical services, hospital relations, hiring of professional staff, marketing and all other aspects of practice management.

1998 - 2001: Expanded above practice to include private freestanding, state-of-of-the-art facilities in Charlottesville and Richmond Virginia with affiliations in other locations.

2001 - Present: President and CEO of the Center for Pain Relief, Tri-State, PLLC a regional Spine and Pain Management Center formed in partnership with St. Mary's Medical Center in Huntington, WV to provide Spine Care and Interventional Pain Services to western West Virginia, eastern Kentucky and southern Ohio.

1997 - Present: David L. Caraway, M.D., Ph.D., P.L.L.C. Established firm to provide consulting, lecturing, and compliance planning with the mission of elevating the field of pain management through education, development and deployment of new therapies while promoting "best practice" strategies. The corporation has worked with private practitioners, hospitals, legal organizations, regulatory offices, insurance providers, medical device manufacturers, and pharmaceutical companies.

Anesthesiology

1996 - 2000: Professional Anesthesia Services, Inc.

Provided services as an anesthesiologist in general practice and supervision of **nurse** anesthetists including thoracic, obstetrical, pediatric and neurosurgical anesthesia.

Employment

2000 - present: David L. Caraway, M.D. Ph.D., General Anesthesiology Services.

Independent contracting and consulting to provide general anesthesia services and training.

April 2014 – Present: Chief Medical Officer Nevro Corporation 4040 Campbell Avenue, Suite 210

Menlo Park CA 94025 Telephone: 650.433.3219 Mobile: 650.400.9101

CURRENT MEDICAL SOCIETY LEADERSHIP ROLES:

American Society of Interventional Pain Physicians

Immediate Past Vice President

North American Neuromodulation Society

Immediate Past Vice President

PROFESSIONAL MEMBERSHIPS:

North American Neuromodulation Society

American Society of Interventional Pain Physicians

American Academy of Pain Medicine Neuromodulation Therapy Access Coalition International Society for the Study of Pain American Society of Anesthesiologists Virginia State Society of Anesthesiologists West Virginia State Society of Anesthesiologists

American Medical Association

CERTIFICATION: Virginia Medical License: 54348

West Virginia Medical License: 18714 Ohio Medical License: 35-086568

Diplomat of American Board of Anesthesiology Diplomat American Board of Medical Examiners

DEA BC 7126142 (WV)

PRESENTATIONS:

PUBLICATIONS, RESEARCH, Director of Research with extensive clinical research background as Primary Investigator in many national trials and clinical

studies. Consultant to Industry and the FDA on trial design and implementation. List of research projects available upon request.

List of recent peer-reviewed publications attached. Over 300 national and international medical society presentations, poster

presentations and symposia.



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INTRATHECAL DRUG DELIVERY FOR CHRONIC PAIN LITERATURE REVIEW*

April 2008

Intrathecal drug delivery systems provide targeted drug delivery for chronic, intractable pain. Please see the brief summary on pages 15-16. The intent of this summary is to present data from published scientific literature relating to clinical and cost-effectiveness of intrathecal drug delivery (IDD) for chronic, intractable pain. Medtronic provides this information for your convenience only. It is not intended as a recommendation regarding clinical practice. It is the responsibility of the provider to determine coverage and to submit appropriate codes, modifiers, and charges for the services that were rendered. Contact your local fiscal intermediary/payor for interpretation of coverage, coding, and payment policies and before seeking reimbursement for use of a product that may be inconsistent with or not expressly specified in the FDA-cleared or -approved labeling (see the product technical manual). Contact Medtronic Coverage and Authorization Services at 1-800-292-2903.

Overview

Opioid receptors were discovered in the central nervous system in the 1970s.^{1,2} Soon thereafter, many studies were showing that when morphine is infused into the cerebrospinal fluid close to the spinal opioid receptors, it produces analgesia at a much lower dosage** and with fewer or milder adverse effects than when it is administered systemically.³⁻⁹ Consequently, intrathecal opioid infusion, or intrathecal drug delivery (IDD),*** has become an option for alleviating chronic pain, initially of cancer origin and later of noncancer origin, in patients who fail to respond to conventional pain therapies or do not tolerate systemic opioids due to their adverse effects. 4-6,10-12

IDD for chronic pain is achieved with an implantable system that consists of an infusion pump and an intraspinal catheter. The pump, which has a fluid reservoir, is placed in a subcutaneous pocket in the anterior abdominal wall. The catheter is inserted into the intrathecal space of the spine, tunneled under the skin, and connected to the pump. The reservoir is refilled by a needle inserted through the skin. The IDD system in greatest use has a battery-operated pump, which is programmable with a hand-held telemetry device that can set the pump to deliver a constant infusion, a greater infusion during certain periods of the day, or a single dose of drug at a specific time or times of the day. Also, the pump can store and telemeter data on the patient, the drug being infused, the pump's programming, reservoir volume, and performance data, and provide an audible signal when its battery power, reservoir volume, or temperature are below set thresholds. An IDD system with a non-programmable, constant-flow pump may be indicated when the infusion rate will be constant day and night.

Implantation of an IDD system should follow a successful trial of intraspinal opioid administration by epidural or intrathecal injection, or by epidural or intrathecal infusion using an external pump.

Intrathecally administered opioids, such as morphine, can relieve neuropathic pain from irritation of a nerve root or peripheral nerve, nociceptive pain from irritation of pain-sensitive nerve fibers, and deafferentation pain from destruction of an ascending sensory system. 9,10,13 Morphine and alternatively ziconotide, a calcium channel blocker with analgesic properties, are the only drugs approved by the Food and Drug Administration (FDA) for intrathecal infusion for pain.

Serious complications of IDD system implantation, such as meningitis and wound infection may occur, 3,48,14 Intrathecal morphine can produce generally tolerable and self-limiting adverse effects, most commonly pruritis, nausea and vomiting, urinary retention, and constipation, due to its direct contact with opioid receptors in the central nervous system.^{3,4,6,8} A noninfectious, granulomatous mass, which has been associated with morphine infusion, can develop at the tip of the infusion catheter to limit IDD and, if undiagnosed, produce neurologic injury including paralysis. 14-16

^{*}The Literature Review was authored by Douglas E. Busby, MD. Dr. Busby, a former Medicare contractor medical director, is a Medtronic consultant.

^{**}For a given analgesic effect, Emg of intraffrecal morphine is equivalent to about 300 mg of our arouphine or about 100 mg of intravenous morphine 347

^{***} A broader term that encompasses opioids and various adjuvant medications.

NEUROSTIMULATION FOR CHRONIC PAIN

Overview (continued)

IDD is widely used in the United States for controlling chronic pain, most frequently failed back surgery syndrome (FBSS). In this paper, results of studies of IDD, published in the peer review scientific literature, are summarized and reviewed to determine the effectiveness and cost of IDD.

Effectiveness of IDD for Chronic Pain

Table 1 summarizes 12 studies of the effectiveness of IDD for chronic pain, reported from 1991 to 2006. Although patient selection criteria varied considerably, all of these studies required that patients have pain refractive to medical or surgical therapies, or have intolerable adverse effects from systemic opioids. Exclusion criteria included major psychiatric disorders, drug habituation problems and unresolved issues of secondary gain, which can have a negative impact on pain management.

Most of these studies assessed IDD effectiveness by measuring pain intensity before and after IDD system implantation with a numerical pain rating (NPR) scale or visual analog scale (VAS). Use of an NPR scale involves the patient giving a numerical assessment of pain severity usually between zero for "no pain" and 10 for "worst possible pain," and use of a VAS involves the patient placing a mark usually on a 10-cm line between 0 cm for "no pain" and 10 cm for "worst possible pain." Many studies also determined the patients' preand postimplantation physical functioning and disability levels, intake of analgesics and satisfaction with IDD.

Table 1: Effectiveness Data from IDD Studies for Chronic Pain

Author(s)	Description	Results
Doleys DM, et al.,	Retrospective study of three groups of patients with FBSS, who were matched on a number of demographic and pain variables, although the average duration of pain	The patients in the IDD group had implantation of a programmable IDD system.
2006,17	was significantly different among the groups (P < 0.01). One group of 50 patients had been implanted with an IDD system (IDD group), another group of 40 patients had completed a 4-week residential pain and rehabilitation program (rehabilitation group), and another group of 40 patients had received standard medical therapy that emphasized use of oral opioids (oral opioid group). All of these patients had pretreatment pain ≥ 2 years, which was primarily in the lumbar spine and associated or not associated with leg pain, was predominantly nociceptive or mixed neuropathic-nociceptive, and had been treated with one or more lumbar surgeries. The IDD group had undergone a trial period with epidural morphine for up to 2 weeks. The criteria for	The average follow-up for each group was about 4 years. The average pretreatment pain rating on the NPR scale was significantly greater for the IDD group than the rehabilitation group (P < 0.001), but not the oral opioid group. Follow-up NPRs had decreased by 35.5% in the IDD group, 8.0% in the rehabilitation group, and 8.5% in the oral opioid group, with the
		decrease being significant only in the IDD group (P < 0.001). In all 3 groups, pain sensation remained in the "moderate" range, depression remained in the "mild to moderate" range, and disability remained in the "severe" range, with little
		evidence of improved quality of life or physical functioning. The percentage of patients working at follow-up was 26% in the IDD group, 23% in the rehabilitation group and 10% in thoral opioid group (P = N.S.).
	implantation of the IDD system were ≥ 50% relief of pain on an NPR scale, decrease in the use of oral analgesics, increased activity level or decreased level of discomfort with typical activities of daily living or work, absence of untoward side effects, absence of significant psychopathology, and appropriate expectations.	The IDD and oral opioid groups reported 64% and 52% overal improvements in pain, respectively, which were significantly greater than the 27% improvement in pain reported by the rehabilitation group (P < 0.001). Treatment was rated "good" ("excellent" by 88% of the patients in the IDD group, 51% of the patients in the rehabilitation group and 97% of the patients
	Effectiveness of the implanted IDD system was evaluated ≥ 3 years after system implantation with questionnaires	in the oral opioid group, with the IDD and oral opioid groups differing significantly from the rehabilitation group (P $<$ 0.001
	and a telephone interview by a disinterested third party. Pain was assessed with the NPR scale. The questionnaires were used to evaluate pain sensation, functional abilities, depression, disability, work status, medication use, health	In the IDD group, the average level of intrathecal opioid use increased from 3 mg morphine equivalent to 21 mg morphine equivalent over the course of the follow-up period.
	status and satisfaction with therapy.	Whether complications occurred in this study was not reporte

Table 1: Effectiveness Data from IDD Studies for Chronic Pain

Author(s)	Description	Results
Thimineur M, et al., 2004. ¹⁸	Prospective study of 88 implantable IDD system candidates, whose pain intensity was judged to be severe and significantly impacting upon physical condition and quality of life, and conservative therapies for pain had been exhausted. Also, pain had to be opioid responsive, with doses required to control pain causing side effects, and psychological evaluation did not indicate a major psychiatric disorder.	Of the 88 patients who had trial IDD, 44 patients had implantation of a programmable IDD system and 44 patients underwent unsuccessful trial IDD or for other reasons declined IDD. At 3 years, 38 patients remained in the IDD group and 31 patients remained in the non-IDD group. The newly referred group of 59 patients declined to 41 patients at 3 years.
	All patients underwent a 3-day inpatient trial of intra- thecal morphine therapy. The criterion for implantation of an IDD system was ≥ 50% pain relief on a VAS without severe side effects.	At 3 years, pain level on the VAS had decreased by 27% in the IDD group of patients ($P < 0.000001$), and had increase by 7% in the non-IDD group ($P < 0.01$). These findings were reflected in the other pain measures.
	After trial IDD, three groups of patients were formed: IDD patients, non-IDD patients who underwent an unsuccessful trial or for other reasons declined IDD, and newly referred patients who agreed to participate in the study. All patients received other pain therapies per standard of care in the practice. Effectiveness of the implanted IDD system was evaluated by having IDD and non-IDD patients complete the VAS for pain level and questionnaires at baseline and at 6-month intervals for 3 years, and newly referred patients complete the VAS for pain level and the same questionnaires at baseline and at 3 years. The questionnaires were used to evaluate functional abilities, anxiety, depression, and disability. Since this study did not conform to random assign-ment of subjects, separate data analyses were conducted for each patient group studied. Analyses for the IDD and non-IDD groups used the intention-to-treat principle.	At 3 years, anxiety had improved significantly in the IDD group of patients (P < 0.001), and had worsened significantly in the non-IDD group of patients (P < 0.01).
		A depression scale and a depression inventory showed significant improvement in the IDD group (P < 0.001 and P < 0.01, respectively), and significant worsening in the non-IDD group (P < 0.01 and P < 0.001, respectively).
		At 3 years, physical functioning had not changed significantly in the IDD and non-IDD groups of patients. However, disability had improved significantly in the IDD group ($P < 0.01$), and had worsened significantly in the nor IDD group ($P < 0.05$).
		In contrast to the non-IDD group of patients, all of these parameters had significantly improved in the newly referre group of patients (P < 0.000001).
		At 36 months, the IDD group of patients was still "worse off than the newly referred group were at baseline.
		Pump pocket infections occurred within 1 month postoperatively in 2 patients, requiring IDD system remova and replacement after antibiotic therapy. Catheter revision was necessary in 1 patient due to kinking of the catheter. Transverse myelitis at the catheter tip was diagnosed in 1 patient at 47 months after implant, necessitating IDD system removal and high-dose steroid treatment to which the patient had a good response.

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Deer T, et al., 2004. ¹⁹	Multicenter prospective study of 166 implantable IDD system candidates with chronic low back pain, with or without leg pain, but with greater low back pain than leg pain. Each participating center followed its standard clinical	Of the 166 patients who were enrolled for this study, all had back pain, and many had more than one cause of their pain, with 66.2% suffering from FBSS, 36.8% from degenerative disc disease and 28.7% from radicular leg pain. Patients with back surgeries had undergone an average of 2.8 procedures.
	practice for patient selection, trialing method and criteria for definition of a successful trial, implant method for the IDD system, and postimplantation	Of the 166 patients who underwent trial intrathecal morphine therapy, 136 (82%) patients had implantation of a programmable IDD system. The mean trial duration was 3.5 \pm 5.4 SD (standard deviation) days.
	assessed at 6 and 12 months after system implantation with an NPR scale for evaluating low back and leg pain, and questionnaires for evaluating functional abilities, disability, work status, use of systemic opioids, and satisfaction with IDD.	At the 6- and 12-month follow-up evaluations, NPRs had decreased significantly both for back and leg pain (P < 0.001) compared to baseline. At 12 months, back pain had declined by 48% and leg pain by 32%.
		At 6 and 12 months, improvement in functional abilities had occurred in 60% and 66% of the patients, respectively.
		At baseline, 30% of the IDD patients had minimal-to-moderate disability and 60% of them had severe disability. At 6 and 12 months, 65% and 73% of the IDD patients had minimal-to-moderate disability, respectively, and 30% and 22% of them had severe disability, respectively.
		At baseline, 54.5% of the IDD patients (total $n=134$) were not working, 25.4% were retired, 9% had a status of not working, 7.5% of them were working at reduced capacity or hours due to pain, and 3.7% were working. At 12 months, 68.1% of the IDD patients (total $n=47$) remained at the same work status, 21.3% had a better work status, and 10.6% had a lower work status.
		At baseline, 88.2% of the IDD patients (total $n=154$) were taking systemic opioids. At 12 months 42.5% of them (total $n=75$) had decreased or ceased their use of systemic opioids.
		At the 12-month evaluation, 60 of the 75 (80%) of the IDD patients stated that they were satisfied with this therapy and 65 (87%) of them said that they would have IDD again.
		Adverse events occurred in 23 of the 154 (14.9%) patients who received IDD system implantation. Of these patients, 21 required some surgery to correct the problem. Adverse events included infection (2.2%), catheter dislodgement (1.5%), catheter fracture (0.7%) and reaction to medication (5.1%).

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Raphael JH, et al., 2002. ¹¹	system implanted for mechanical low back pain (LBP) or FBSS ≥ 6 months previously and then continued to have the system's pump refilled at the authors' pain center. Effectiveness of the implanted IDD system was assessed with a mailed questionnaire that asked patients to rate pain and various quality of life measures on VASs. Pain was additionally evaluated for its severity using a 4-point verbal scale for its severity ("none," "mild," "moderate," or "severe"). The questionnaire also asked about analgesic use, general practitioner (GP) visits, work status and patient satisfaction with IDD. After this data was analyzed by an independent reviewer, information on the patients' diagnosis, IDD system implantation, and subsequent care were determined from their medical records.	Thirty-six of the 37 (96%) patients responded to the questionnaire. Thirty-four patients had implantation of a programmable IDD system, and 2 patients had implantation of a patient-controlled IDD system. Of the 36 patients, 12 patients had LBP and 24 patients had FBSS, with a median of 2 spinal operations (range 1–11) per patient. The 36 patients had the IDD system implanted for a mean of
		4.38 ± 3.03 SD years (range, 0.5–9.0 years). Medical records of the 37 patients who were sent the questionnaire showed that the intrathecal drug was diamorphine in all patients, bupivacaine in 32 patients, clonidine in 27 patients and baclofen in 3 patients.
		Pain measures showed significant improvement in both the LBP and FBSS patient groups (P < 0.005). The NPR had improved by 33% in the LBP group and by 47% in the FBSS group.
		Quality of life measures had improved significantly in the FBSS group (P < 0.005), except for work interruption and the effect of pain on sex life. The same measures had changed in the LBP group, but not significantly.
		Of the 15 patients under age 50, none were able to return to work before having implantation of an IDD system, but 4 (27%) patients were able to return to work after implantation.
		The median number of general practitioner visits per month in the FBSS group had decreased from 2.24 pre-IDD to 0.72 post-IDD ($P < 0.05$), and in the LBP group had decreased from 2.07 pre-IDD to 0.90 post-IDD ($P = N.S.$).
		Overall, IDD was considered worthwhile by all but 1 of 5 patients with 26 patients responding that it was very worthwhile, 5 patients responding that it was quite worthwhile, and 3 patients responding that it was adequate.
		Complications required a total of 10 revision surgeries, 3 due to catheter problems, 4 due to pump position problems, 2 due to infection, and 1 due to cerebrospinal fluid leak.

 Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Kumar K, et al., 2001. ¹⁰	candidates with severe, chronic, noncancer pain, who were referred by a multidisciplinary pain management clinic for possible continuous intrathecal morphine therapy. All of these patients had pain that was refractory to conservative management and were consuming narcotic analgesics regularly when they entered the study. Inclusion criteria were known organic benign cause of pain, poor pain control despite pharmacotherapy and other pain therapy measures including transcutaneous electrical nerve stimulation (TENS) or spinal cord stimulation (SCS), if indicated, and exclusion of psychiatric illness and medicolegal issues. All patients underwent trial intrathecal morphine therapy for up to 2 weeks after having a favorable response to a double-blind intrathecal morphine test. The criterion for implantation of an IDD system was ≥ 50% pain relief on a VAS without undesirable side effects.	Of the 25 patients who underwent trial intrathecal morphine therapy, 16 (64%) patients had implantation of a programmable IDD system. Four of the implanted patients had neuropathic pain, 3 had nociceptive pain, 8 had mixed neuropathicnociceptive pain, and 1 had deafferentation pain.
		At a mean follow-up period of 29.14 ± 12.44 SD months (range, 13–49 months), 14 patients were still receiving intrathecal morphine. The IDD system had been explanted from 2 patients because of intolerable side effects.
		At last follow-up, 12 of the 16 (75%) patients were considered successes in having \geq 25% pain reduction on the VAS. Also, 7 of the 16 (44%) patients had \geq 50% pain reduction on the VAS.
		At last follow-up, patients with neuropathic pain had less pain reduction (37%) than patients with nociceptive or mixed neuropathic-nociceptive pain (57% and 61%, respectively). The patient with deafferentation pain had the greatest pain reduction (75%).
		At last follow-up, 9 of the 16 (56%) patients had increased daily activities after years of leading passive lives. However, the 9 patients did not have a significant increase in return to
	evaluated every 6 months after system implantation by an independent physician, who determined pain relief with a VAS and pain questionnaire, and documented activity level and use of drugs in conjunction with intrathecal opioids. Patients who had ≥ 25% pain relief on the VAS were considered successful responders to this therapy.	employment. One pump was replaced because of pump failure and 2 pumps were explanted due to intolerable side effects of the drug being delivered. Disconnection of the catheter from the pump in 1 patient was corrected operatively, and infection of the pump pocket in 1 patient was treated successfully with intravenous antibiotics.
	Statistical analyses used the intention-to-treat principle.	

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Roberts LJ, et al., 2001. ²⁰	Retrospective study of 88 patients with chronic noncancer pain, treated at 2 pain management centers with implanted IDD systems.	Of the 88 patients who had an implanted IDD system, 55 patients had FBSS, with a mean of 4 spinal surgeries (rang 1–18 surgeries). Of the 88 patients, 85 had implantation of programmable IDD system and 3 patients had implantat
	assessment and an intrathecal opioid trial prior to IDD system implantation. Of the 78 patients for whom trial data was available, 25 patients had intrathecal infusion, 21 patients had intrathecal boluses, 21 patients had epidural infusion, 8 patients had epidural boluses, and 3 patients had self-administered intrathecal boluses during their trial periods. The methods used to evaluate trial outcome were not reported. Effectiveness of the implanted IDD system was assessed with a mailed questionnaire, which asked patients to rate pain relief on an NPR scale, change of activity levels on a 5-point categorical scale, and satisfaction with IDD on a 6-point categorical scale, and to list current use of medications.	of a non-programmable, constant-flow IDD system. Questionnaires were returned by 67 patients (80% of those alive) at a mean follow-up period of 36.2 ± 2.4 (SD) months. Pain relief was ≥ 50% on the NPR scale in 40 of 49 (82%) reporting patients, with the mean pain relief in the 49 patients being 60.0%. Activity levels had increased in 36 of 49 (74%) reporting patients. However, work status of the 49 patients had remained unchanged.
		Current use of analgesic medications by 48 reporting patients had declined significantly (P < 0.0001). Of 51 reporting patients, 43 (84%) patients were very or moderately satisfied, 2 (4%) were slightly satisfied, and 3 (6% patients were very or moderately dissatisfied with IDD.
		Information on technical complications was available on 81 of the 88 (92%) patients. At least one procedure to correct a surgical problem was necessary in 32 of the 81 (40%) patients. Complications involving the catheter included catheter dislodgement in 12 of the 81 (15%) patients, nerve root irritation in 3 (4%) patients, catheter occlusion in 8 (10% patients, and catheter disconnection in 10 (12%) patients. Th pump had to be repositioned in 5 (6%) patients for various reasons, including pressure on the lower ribs and rotation, and replaced in 8 (10%) patients due to pump malfunction. A wound hematoma had to be surgically drained in 1 (1%) patient. Clinical signs of wound infection occurred in 5 (6%) patients, with resolution of signs while they were treated with oral antibiotics. Meningitis in 1 (1%) patient led to IDD system removal, treatment with intravenous antibiotics and system replacement.

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Anderson V, Burchiel K, 1999. ²¹	Prospective study of 40 consecutive implantable IDD system candidates who had been suffering for ≥ 6 months from chronic noncancer pain that was refractory to medical or surgical therapies, had sensory loss in an anatomic distribution, and had no contraindications to surgery, psychopathological or substance abuse problems, or unresolved issues of secondary pain. All patients underwent trial of intrathecal morphine	Of the 40 patients who underwent trial IDD therapy, 30 (7 patients had implantation of a programmable IDD system Ten of the implanted patients had peripheral neuropathic pain (from arachnoiditis, thoracotomy, radiation or other chronic peripheral nerve irritation), 1 patient had nocicep pain (from coccydynia), 15 patients had mixed neuropath nociceptive pain (from FBSS in 14 patients), and 4 patients had deafferentation pain (from stroke, limb amputation, paraplegia or rhizotomy).
	therapy. Fourteen patients received an intrathecal injection and 26 patients received an epidural infusion for 2–3 days. The criterion for implantation of an IDD system was ≥ 50% pain relief on a VAS.	Pain levels assessed with VAS were significantly decreased at all evaluations in the 24-month follow-up period (P = 0.002). At 24 months, 8 of the 22 (36%) patients who could be followed had ≥ 50% pain reduction, which was reflected
		in the pain questionnaire. Inclusion of 5 patients who continued IDD therapy but were lost to follow-up yielded a 24-month success rate of 30%. The comparable data for ≥ 25% pain reduction were 50% and 41%, respectively.
		Pain-related functional limitation, ability to cope with pain, sleep, social activities and inactivity levels all showed improvement or a trend toward improvement throughout follow-up.
		Before IDD therapy, 14 of the 30 (47%) patients were considered disabled, and after 24 months, 7 of 20 (35%) patients were considered disabled, and 13 of the 20 (65%) patients were not disabled (p > 0.05).
		At study entry, 28 of 30 (93%) patients were taking systemic opioids regularly, and at 24 months, 6 of 20 (30%) patients were taking systemic opioids to supplement intrathecally infused opioids. The remaining 14 (70%) patients were using intrathecally infused opioids as their only analgesic.
		Five of the 25 (20%) patients reported 7 device-related complications that required 5 repeat operations. Catheter migration in 2 patients, catheter obstruction in 1 patient, and cerebrospinal fluid tracking along the catheter with seroma formation in 2 patients were corrected without further complications. Pump malfunction in 2 patients, in 1 patient due to pump rotation with coiling of the catheter, led to pump replacement without further complications.

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Brown J, et al., 1999. ²²	Retrospective study of 38 patients who had an IDD system implanted by the same surgeon for intractable noncancer pain ≥ 3 years previously.	The 38 patients had implantation of a programmable IDD system. At the time of implantation, 33 (87%) patients were suffering from FBSS or intractable back pain, and 5 (13%)
	All of these patients had undergone 2–3 epidural steroid injections to rule out a significant inflammatory component of their pain, followed by a single	patients a combination of FBSS and radiculopathy. The average number of pain-related surgeries was 3.03 (range, 0–6) per patient.
	epidural dose of morphine to ensure appropriateness for an epidural morphine trial. The trial had lasted, in general, up to 2 weeks. The criteria for implantation of the IDD system were: ≥ 50% relief of pain on an NPR scale; increased activity level or decreased level of	At an average follow-up of 4.15 \pm 0.13 SEM (standard error of the mean) years, the mean pain rating on the NPR scale was significantly lower than reported before IDD (P < 0.001). It had not changed during IDD, still remaining at a substantial level throughout the follow-up period.
	discomfort with typical activities; absence of untoward side effects; absence of significant psychopathology; and appropriate expectations.	Also at follow-up, questionnaires indicated, on the average, a high pain level, mild level of depression, and a severe disability level. On retrospective questioning, however, 24
	Effectiveness of the implanted IDD system was evaluated with questionnaires and a telephone inter- view by a disinterested third party. Pain was assessed by having patients rate their pain on the NPR scale over	of the 38 (64%) patients reported improvement in their pain and 18 of the 38 (48%) patients reported improvement in their functioning. Moreover, 34 of the 38 (89%) patients reported "good-to-excellent" satisfaction with long-term IDD
	a 6-month period. The questionnaires were used to evaluate pain sensation, functional abilities, depression, disability, work status and satisfaction with therapy.	Twenty-nine of the 38 (76%) patients reported IDD system-related complications that ultimately resulted in surgical intervention. The majority of them were due to catheter problems.
Tutak U, Doleys DM, 1996. ²³	Prospective study of 26 patients with an implanted IDD system for chronic noncancer pain that had not responded to more conservative measures and would not be relieved by surgery. All of these patients had received 2–3 epidural steroid injections, followed by a single epidural dose of	The 26 patients had implantation of a programmable IDD system. At the time of implantation, all patients had pain in the low back and in one or both legs. Twenty-two patients had FBSS with an average of 3.8 low back operations (range, 0–10 operations), 1 patient had chronic regional pain syndrome (CRPS) with 5 lumbar operations, 1 patient had ankylosing spondylitis, and 2 patients had spondylolisthesis.
	morphine to ensure relief of pain and recurrence of it. Then they had a trial with epidural morphine generally lasting up to 2 weeks. The criteria for implantation	The average follow-up period was 23 months (range, 16–27 months).
	of the IDD system were ≥ 50% relief of pain on an NPR scale; discontinued use of analgesics, especially oral narcotics, during the trial; increased activity level or decreased level of discomfort at a typical activity level; absence of untoward side effects; absence of significant psychopathology such as severe personality disorder or psychosis; and appropriate expectations.	At 12 months after IDD system implantation, the average pain rating on the NPR scale had decreased by 44.9%, the average overall activity level had increased by 50%, and 77% patients rated their overall satisfaction with IDD as good to excellent. Overall improvement was rated by the physician o clinic nurse as excellent in 5 (19%) patients and as good in 27 (81%) patients.
	Effectiveness of the implanted IDD system was evaluated at times of pump refill, with questionnaires and with a telephone interview conducted by a disinterested third party. Patients rated their pain on	At the 12-month follow-up, the average daily oral morphine equivalent had decreased from 289 mg per day to 175 mg per day.
	the NPR scale, percent improvement in overall activity level and overall satisfaction with IDD. Oral narcotic use was estimated for 1 week before the trial period and at follow-up.	Nine of the 26 (35%) patients had catheter-related complications requiring surgical correction. Eight of them were due to catheter collapse and 1 due to catheter breakage. One extremely slim patient had erosion of skin over the pump, necessitating pump removal.

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Winkelmüller M, Winkelmüller W, 1996. ⁹	Retrospective study of 120 patients who had an IDD system implanted for opioid therapy of chronic non-cancer pain ≥ 6 months previously. Patient selection criteria had included: unsuccessful treatment of the underlying cause of the pain; somatically caused pain; unsatisfactory response to peripheral or central analgesic drugs or intolerable drug side effects; failure of other pain therapies such as TENS or SCS; exclusion of psychiatric illnesses; and pension applications or suits for damages currently under consideration. All of the patients had undergone a trial period of intrathecal morphine therapy. The criterion for implantation of an IDD system was ≥ 60% pain relief on a VAS without undesirable side effects. Effectiveness of the implanted IDD system was assessed at 6 months with a questionnaire that asked patients to record pain on a VAS, and activity level,	A non-programmable IDD system had been implanted in 119 patients and a programmable IDD system had been implanted in 119 patients and a programmable IDD system had been implanted in 1 patient. Seven of these patients had neuropathic pain, 13 patients had nociceptive pain, 73 patients had neuropathic-nociceptive pain, and 27 patients had deafferentation pain. At a mean follow-up period of 3.4 ± 1.3 SEM years (range 0.5 5.7 years), 82 patients were still receiving intrathecal opioid therapy with a functioning implant. Five of these patients had neuropathic pain, 10 patients had nociceptive pain, 49 patients had neuropathic-nociceptive pain, and 18 patients had deafferentation pain. With respect to the other 38 patients, 25 patients had IDD system explantation for variou reasons, 2 patients had discontinuance of therapy because of secondary illnesses that had to be treated, 4 patients had replacement of the opiate with sodium chloride due to aftercare physician concern for use of addictive substances, and 7 patients had died of causes unrelated to this therapy.
	mood, and quality of life.	At last follow-up, the VAS for pain intensity had improved by an average of 58%. The best initial reduction (77%) in pain intensity had occurred in the nociceptive group, but at last follow-up, differences in improvement between pain groups were not statistically different.
		Before IDD, 94% of the patients were classified as passive or had socially withdrawn, and at last follow-up, 43% of the patients still classified themselves as "passive and withdrawr The difference between activity scores before and after therapy were statistically significant (P < 0.001).
		Before IDD, 88% of the patients described themselves as despairing and depressed, and at last follow-up, 67% of the patients either were satisfied with their condition or were slightly depressed. The difference between mood scores before and after therapy were statistically significant (P < 0.001).
		At last follow-up, 66 of the 82 (81%) patients reported improved quality of life from IDD therapy, and 75 of the 82 (92%) patients were satisfied with this therapy.
		Twenty-five of the 120 (21%) patients had catheter disconnections and dislocations requiring surgical correction Fourteen pumps had to be replaced for technical reasons, such as skin perforations, irregular rates of flow, and serious incidents that occurred while refilling a pump type in which the drug and bolus chambers were accessible only via a single diaphragm. Two pumps were replaced due to infections in the vicinity of the pump pocket.

Table 1: Effectiveness Data from IDD Studies for Chronic Pain (continued)

Author(s)	Description	Results
Hassenbusch SJ, et al., 1995. ²⁴	system candidates who had a ≤ 25% pain reduction on an NRS scale. All of them had only neuropathic pain with no other treatment options for it. Exclusion criteria included a psychiatric or personality disorder that would prevent successful treatment, an addictive personality, and a mental or true allergy to intrathecal drug being administered. All of the patients had a 2- to 5-day trial. The criterion for IDD system implantation was > 50% pain relief on the NRS scale.	Of the 22 patients, 18 (82%) had implantation of a programmable IDD system. Pain was caused by arachnoiditis in 9 patients, chronic neuropathy in 3 patients, traumatic intercostal neuralgia in 2 patients, phantom limb pain in 1 patient, CRPS in 1 patient, lumbosacral plexopathy in 1 patient and spinal cord injury in 1 patient.
		At a mean follow-up of 2.4 ± 0.3 SEM years, 6 of the 18 (33%) patients had a good NRS outcome and 5 of the 18 patients (28%) had a fair NRS outcome, so that 11 of the 18 (61%) patients had a successful NRS outcome. These patients reported an average pain reduction of 56%. Seven of the 18 patients had poor or no pain relief.
	Patients with the implanted IDD system were last evaluated within 2 months of final analysis of the patients in this study, or if IDD had been a failure, at the time that IDD was stopped or the system removed. Effectiveness of the implanted IDD system was	At follow-up, daily activities in the 18 patients with succe outcomes were better for walking, climbing stairs, sleep and eating. Thirteen of the 18 (73%) patients said that the would have the pump placed again.
system by a disinterested third party who obtained pain ratings with the NRS scale and patient estima of pre- and post-implantation pain levels. A success outcome for IDD was defined as ≥ 25% pain relief on the NRS scale, with 25–39% pain relief being considered a "fair" outcome, and ≥ 40% pain relief being considered a "good" outcome. Other outcome measures assessed were activity levels and satisfact	assessed in the patients who still had an operating system by a disinterested third party who obtained pain ratings with the NRS scale and patient estimates of pre- and post-implantation pain levels. A successful outcome for IDD was defined as ≥ 25% pain relief on the NRS scale, with 25–39% pain relief being	Occurrence of complications was not statistically different between success and failure patients. Spontaneous dislocation of the spinal catheter occurred in 3 patients and catheter occlusion from a kink at the fascial-ligamental anchor occurred in another 2 patients. Pump revision due to a shift in pump position was necessary in 2 patients. Pump rotor stall occurred in 1 patient and pump battery depletion occurred in 2 patients. Overall, 6 patients required operative revision due to technical complications.
Kanoff RB, 1994. ²⁵	Prospective study of 15 patients with intractable noncancer pain. All were being treated with large doses of oral and transdermal opioids, but were still having breakthrough pain. Trial IDD before implantation was introduced in the	All of the 15 patients, including the 6 patients who had trial IDD, had implantation of a programmable IDD system. Five patients were suffering from complex regional pain syndrome, 9 from FBSS, and 1 from low back pain with no identifiable cause.
	last 6 patients. The intrathecal catheter for implantation of an IDD system was placed and connected to an external pump, which delivered opiates or a placebo while patients were monitored in an intensive care unit. The criteria for IDD pump implantation were > 50% pain reduction with the opiates and appropriate, consistent responses to placebo challenges.	At a mean follow-up period of 17 months (range, 2–44 months), 8 patients reported that pain relief was excellent, 3 patients that their pain relief was good, and 4 patients that their pain relief was fair.
		None of the 15 patients was working prior to IDD implantation. At last follow-up 6 patients had returned to their former occupations or related levels of vocational activity.
	Effectiveness of the implanted IDD system was evaluated by having patients rate their pain relief as "fair" (≥ 50% pain relief), "good" (> 75% pain relief), or "excellent" (> 90% pain relief). Patients were also asked about their ability to perform certain activities of daily living, work status and their need for supplemental	Also at last follow-up, all of the patients were independent in relation to self care, with all but 2 patients being independently active outside of the home. Only 3 patients required supplemental analgesic medication.
	analgesic medication.	Two of the 15 (13%) patients had migration of their catheters requiring catheter replacement. One of these patients had further surgery to repair a small tear in the replacement catheter.

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Table 1 Summary

Of these 12 studies of IDD for chronic pain, seven are prospective cohort studies, 10,18,19,21,23-25 and five are retrospective cohort studies.9.11.17.2022 One of the retrospective studies17 compared three matched groups of patients, one group having been implanted with an IDD system, another having completed a 4-week residential pain and rehabilitation program, and another group having received standard medical therapy that emphasized use of oral opioids. In seven studies where results of trial IDD were reported, 10,19,21,23,24,25 an IDD system was implanted in 250 of 285 (88%) total trial-IDD patients (range, 64% to 100% of the trial-IDD patients among these studies). The follow-up of patients with an implanted IDD system was long-term in all 12 studies, averaging 33 months (range, 12 to 53 months). In the seven prospective studies, follow-up averaged 24 months (range, 12 to 36 months), and in the five retrospective studies, it averaged 45 months (range, 36 to 53 months).

In all 12 studies, IDD was effective in controlling chronic pain at long-term follow-up, Eight studies^{9,11,17,18-20,23,24} found that IDD decreased pain intensity by 27% to 60% in 471 total patients, in five of these studies9,19,20,23,24 by 45% to 60%. Four studies^{10,20,21,25} found that IDD provided pain relief of 50% or more in 70 of the

102 (69%) total patients. In four studies, ^{17,22,23,25} 109 of the 129 (84%) total patients reported good-to-excellent results from IDD, and in five other studies, 9,11,19,20,24 225 of the 261 (86%) total patients reported satisfaction with IDD.

In the 11 studies that assessed the effectiveness of IDD on physical functioning, nine studies^{9-11,19-24} found that IDD improved physical functioning, and two studies^{17,18} found that it did not. IDD was also associated with decreased disability,^{18,19,21} improved work status, 11,19,25 and reduced use of systemic opioids. 17,19-23,25

Ten of the 12 studies specifically described what complications occurred in 535 patients; 9,10,11,18-21,23-25 Catheter-related problems, including migration, kinking, disconnection, and occlusion, occurred in 16% of these patients, Pump-related problems, including pump pocket infection, pump shift in position, and pump malfunction and failure, occurred in 8% of patients.

Finally, results of the retrospective, comparative study conducted by Doleys and colleagues¹⁷ showed that a group of patients who received IDD had a significant decrease in pain intensity, whereas groups of patients who participated in a 4-week residential pain and rehabilitation program or received standard medical therapy that emphasized use of oral opioids did not.

Cost of IDD for Chronic Pain

Table 2 summarizes three studies on health care costs associated with IDD for chronic pain and cancer pain, reported from 1991 to 2002. Although these studies determined and compared health care costs for IDD and conventional medical management of this pain using different fee schedules and currencies that do not equate to 2008 United States dollars, they illustrate changes in the cost of IDD over time and how IDD compares to the cost of conventional medical management or epidural drug delivery from an external system.

Table 2: Studies of the Cost of IDD for Chronic Pain and Cancer Pain

Author(s)	Description	Results
Kumar K, et al., 2002. ²⁶	Calculated the actual 5-year health care costs in year 2000 Canadian dollars for 23 FBSS patients who had IDD with an implanted, programmable system and 44 matched FBSS patients who had conventional pain therapy, in Saskatchewan, Canada. Accumulative cost data for the IDD group included pump replacement due to battery depletion in the fifth year.	The mean cumulative 5-year health care cost for the 23 patients who had IDD was Canadian \$29,410 (\$5,882 per year), which included \$15,730 for initial implantation and \$13,680 for cumulative 5-year maintenance. The mean cumulative 5-year health care cost for the 44 patients who had conventional pain therapy was \$38,000 (\$7,600 per year).
		The mean cumulative 5-year health care cost for 5 patients who had no complications associated with IDD was \$28,264, and for 14 patients who had 1 or more complications associated with IDD was \$31,131.
		The initially higher health care cost for patients with IDD than for conventional pain therapy would have been recovered by 28 months. Thereafter, the cost of conventional pain therapy would have exceeded the cost of IDD, despite pump replacement in the fifth year.
de Lissovoy G, et al., 1997. ²⁷ Hassenbusch SJ, et al., 1997. ²⁸	Used a decision analytic model to estimate direct health care costs in year 1994 US dollars for patients with FBSS, who had IDD with an implanted system or alternative (medical) therapy over a 60-month period. These costs were projected for a simulated cohort of 1,000 patients with FBSS. They were based on a health insurer paid claims perspective, discounted at a 5% annual rate.	With costs and adverse event rates at base case values, the expected 60-month total cost for IDD was \$82,893 (\$1,382 per month). The best case and worst case costs were \$53,468 (\$891 per month) and \$125,102 (\$2,085 per month), respectively. By comparison, the cumulative 60-month total cost for conventional medical management was \$85,186 (\$1,573 per month).
	Total IDD-related costs for a "base case" were estimated by developing a detailed list of physician and hospital services, and charges for them in 1994 US dollars. Data for calculating the costs of adverse events associated with IDD were obtained from studies on IDD for pain in FBSS and cancer, and were assumed to occur at a constant rate over the 60 months. Data for calculating the cost of pump replacement were based on a median pump life of 48 months, as reported by the pump's manufacturer. Total estimated costs for a "best case" and "worst case" were 65% and 135% of the base case, respectively.	Based on these cost estimates, the cumulative cost for IDD would be less than that for alternative (medical) management after 22 months in the base case and after 12 months in the best case. Moreover, the cumulative cost for IDD would never be less than that for alternative (medical) management in the worst case, averaging \$665 more per month.
	For comparative purposes, charges were estimated for a patient with FBSS who would be a candidate for IDD, but would have alternative (medical) management instead.	
Bedder MD, et al., 1991. ²⁹	Estimated 1-year health care costs in US dollars (year unstated) for 15 patients who had IDD through an implanted, programmable system and 5 patients who had epidural drug delivery from an external system. Of the 15 IDD patients, 8 had noncancer pain and 7 had cancer pain. The 5 epidural drug delivery patients had cancer pain.	The estimated mean 1-year health care cost for the 15 patients who had IDD through an implanted, programmable system was \$21,368, and for the 5 patients who had epidural drug delivery from an external system was \$34,938. At 3 months, the mean health care cost for the patients who had IDD was \$16,316 and for the patients who had
		who had IDD was \$16,316 and for the patients who had epidural drug delivery was \$15,606. At 6 months, these costs were \$18,362 and \$22,050, respectively. Therefore, the cumulative cost for IDD through an implanted, programmable system would be less than that for epidural drug delivery from an external system beyond 3 months.

Table 2 Summary

Two studies^{26,29} used actual cost and one study^{27,28} used a cost model, to determine and compare total health care costs for IDD and conventional medical management for chronic pain and cancer pain. All of the patients in one actual cost study²⁶ and the cost model study^{27,28} had FBSS, whereas patients in the other actual cost study²⁹ had cancer or chronic pain of various origins. The studies showed that the mean first-year cost of IDD, which includes trial IDD and IDD system implantation, becomes substantially less in the second year.

One study²⁶ that used actual cost indicated that IDD became cost-effective, as compared to conventional management, beyond 28 months of its use. The study^{27,28} that used a cost model found that this time period would be in the range of 12 to 22 months for selected patients. Finally, the other study²⁹ that used actual cost showed that beyond 3 months, IDD through an implanted, programmable system would cost less than the cost of epidural drug delivery from an external system.

Conclusions

Long-term clinical studies have shown that IDD is effective in controlling chronic pain, providing pain relief of 50% or more in 36% to 100% of the patients in these studies.

Economic studies have indicated that as compared to conventional medical management of patients with chronic pain, IDD should become cost-effective after about 2 years of use.

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US: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity; chronic intravascular infusion of floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer, Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Contraindications:

Infection; implant depth greater than 2.5 cm below skin; insufficient body size; spinal anomalies; drugs with preservatives, drug contraindications, drug formulations with pH < 3, use of catheter access port (CAP) kit for refills or of refill kit for catheter access, blood sampling through CAP in vascular applications, use of Personal Therapy Manager to administer opioid to opioid-naïve patients or to administer ziconotide.

Warnings:

Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Fallure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose. Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, screening procedures and underdose and overdose symptoms and methods of management, Physicians must be familiar with the drug stability information in the product technical manuals and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion. Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal therapy carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention, including prodromal signs and symptoms of inflammatory mass, Failure to recognize signs and symptoms and seek appropriate medical intervention can result in serious injury or death, Instruct patients to notify their health care professionals of the implanted pump before medical tests/procedures, to return for refills at prescribed times, to carry their Medtronic device identification card, to avoid manipulating the pump through the skin, to consult with their clinician if the pump alarms and before traveling or engaging in activities that can stress the infusion system or involve pressure or temperature changes. Strong sources of electromagnetic interference (EMI), such as short wave (RF) diathermy and MRI, can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient Injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. Avoid using shortwave (RF) diathermy within 30 cm of the pump or catheter. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown, Drug infusion is suspended during MRI; for patients who can not safely tolerate suspension, use alternative drug delivery method during MRI. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively. Confirm pump status before and after MRI. Reference product labeling for information on sources of EMI, effects on patient and system, and steps to reduce risks from EMI.

Precautions:

Monitor patients after device or catheter replacement for signs of underdose/overdose. Infuse preservative-free (intraspinal) saline or, for vascular applications, infuse heparinized solutions therapy at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed programmer may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator).

Adverse Events

Include, but are not limited to, spinal/vascular procedure risks; infection; bleeding; tissue damage, damage to the system or loss of, or change in, therapy that may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose, due to end of device service life, failure of the catheter, pump or other system component, pump inversion, technical/programming errors, or improper use, including use of non-indicated formulations and/or not using drugs or system in accordance with labeling; pocket seroma, hematoma, erosion, infection; post-lumbar puncture (spinal headache); CSF leak and rare central nervous system pressure-related problems; hygroma; radicultits; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; potential serious adverse effects from catheter fragments in intrathecal space, including potential to compromise antibiotic effectiveness for CSF infection; anesthesia complications; body rejection phenomena; local and systemic drug toxicity and related side effects; potential serious adverse effects from catheter placement in intravascular applications. USA Rx Only Rev 0809

www.medtronic.com

United States of America

Medtronic Neuromodulation 710 Medtronic Parkway Minneapolis, MN 55432-5604 USA Tel, 763-505-5000 Toll-free 1-800-328-0810

Europe

Medtronic International Trading Sàrl Route du Molliau 31 Case Postale CH-1131 Tolochenaz Switzerland Tel. +41-21-802-7000

Asia-Pacific

Medtronic International, Ltd.
Suite 1602 16/F
Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4456

Australia

Medtronic Australasia Pty, Ltd., 97 Waterloo Road North Ryde NSW 2113 Australia Tel. +61-2-9857-9000 www.medtronicneuro.com.au

Canada

Medtronic of Canada Ltd. 6733 Kitimat Road Mississauga, Ontario L5N 1W3 Canada Tel. 1-905-826-6020





- 1. Please estimate the number of individuals in your practice that Opioid Therapy is prescribed? 98% of patients (likely thousands of patients)
- Of the total number of individuals you are currently treating for chronic and or malignant pain, please indicate the number that might be candidates for an intrathecal pump.

10-20%

- 3. If a homecare management service was available in the state of Tennessee to assist you in refilling, programming and titrating the intrathecal pump in the home were available would you use it?
 YES
 or
 NO
 (please circle one)
- 4. Would your goal for the patient be reduction and or elimination of oral Opioids for an individual with an intrathecal pump? YES or NO (please circle one)

Please Print Name of Individual Performing the Survey:

Title:

Melissa Perkins PAC

Address of Clinic:

: 353: New Thould Island Rd

ste /223

Hullle TW

37075

- 1. Please estimate the number of individuals in your practice that Opioid Therapy is prescribed? 2000 +
- 2. Of the total number of individuals you are currently treating for chronic and or malignant pain, please indicate the number that might be candidates for an intrathecal pump.

10-20 /0

- 3. If a homecare management service was available in the state of Tennessee to assist you in refilling, programming and titrating the intrathecal pump in the home were available would NO (please circle one) you use it? or
- 4. Would your goal for the patient be reduction and or elimination of oral Opioids for an individual with an intrathecal pump? YES NO (please circle one) or

loon no in formed

Please Print Name of Individual Performing the Survey:

Sha Shaller, MD

Title:

Owner President

Address of Clinic:

2140 No. Thompson Laure Mur Freesboro, TN 37/29

1. Please estimate the number of individuals in your practice that Opioid Therapy is prescribed?
prescribed? Unknown, We are a pain management practice
2. Of the total number of individuals you are currently treating for chronic and or malignant
pain, please indicate the number that might be candidates for an intrathecal pump.
unknown. We are doingtuals currently
3. If a homecare management service was available in the state of Tennessee to assist you in
refilling, programming and titrating the intrathecal pump in the home were available would you use it? NO (please circle one)
 Would your goal for the patient be reduction and or elimination of oral Opioids for an individual with an intrathecal pump? YES or NO (please circle one)
Please Print Name of Individual Performing the Survey: Nancy Vor Miles EN BSN
Title: RN-BSN Back Office Supervisor
Address of Clinic: 6651 Frist Blud #712
Hermiterge TN 37074

- 1. Please estimate the number of individuals in your practice that Opioid Therapy is prescribed? 7500 0 f + 0+01 Plactice
- 2. Of the total number of individuals you are currently treating for chronic and or malignant pain, please indicate the number that might be candidates for an intrathecal pump.
 - 3. If a homecare management service was available in the state of Tennessee to assist you in refilling, programming and titrating the intrathecal pump in the home were available would you use it?

 YES or NO (please circle one)
 - 4. Would your goal for the patient be reduction and or elimination of oral Opioids for an individual with an intrathecal pump? YES or NO (please circle one)

Please Print Name of Individual Performing the Survey: PMMA Sanders, R1

Title:

Address of Clinic: 146 TIM Der (VECK SVITE 200 (OV OVA TN 38018

- Please estimate the number of individuals in your practice that Opioid Therapy is prescribed?
- 2. Of the total number of individuals you are currently treating for chronic and or malignant pain, please indicate the number that might be candidates for an intrathecal pump.

7-10

3. If a homecare management service was available in the state of Tennessee to assist you in refilling, programming and titrating the intrathecal pump in the home were available would you use it?

YES or NO (please circle one)

f Transpertation was an issue

 Would your goal for the patient be reduction and or elimination of oral Opioids for an individual with an intrathecal pump? YES or NO (please circle one)

Please Print Name of Individual Performing the Survey:

Title: Worke Cooperry NID

Address of Clinic:

444 CLINCHFIELD RD KINGSPORT (N) 37660

- 1. Please estimate the number of individuals in your practice that Opioid Therapy is prescribed? 500
- 2. Of the total number of individuals you are currently treating for chronic and or malignant pain, please indicate the number that might be candidates for an intrathecal pump.

- 3. If a homecare management service was available in the state of Tennessee to assist you in refilling, programming and titrating the intrathecal pump in the home were available would (please circle one) you use it? or NO
- 4. Would your goal for the patient be reduction and or elimination of oral Opioids for an individual with an intrathecal pump? YES NO (please circle one) or

Please Print Name of Individual Performing the Survey: BENJAMIN 4. Jo HNSON, WD

Title: MEDICAL DIRECTOR

Address of Clinic: 222 PULASKY ST LAWRENCEBURG, TN 38464



Basic Home Infusion / Implanted Pump Management / PHARMACY & HOME HEALTH LICENSES

STATE	LICENSE TYPE	COMPANY	LICENSE NUMBER	DATE ISSUED	EXPIRATION DATE
Alabama	Pharmacy	BHI	113135	7/14/2008	12/31/2016
Alaska	Pharmacy	ВНІ	1111	5/22/2012	6/30/2016
Arkansas	Pharmacy	ВНІ	OS02253	12/9/2010	12/31/2015
Colorado	Pharmacy	ВНІ	OSP.0005793	2/4/2009	10/31/2016
Connecticut	Pharmacy	BHI	PCN.0000991	11/24/2008	8/31/2015
Delaware	Pharmacy	ВНІ	A9-0000876	7/30/2009	9/30/2016
District of Columbia	Pharmacy	вні	NRX1100423	7/17/2012	5/31/2015
Florida	Pharmacy	ВНІ	5171898	4/20/2007	2/28/2017
Florida	Home Health	IPM	299994328	11/6/2014	11/5/2016
Idaho	Pharmacy	ВНІ	2298MS	1/29/2009	6/30/2015
Illinois	Pharmacy	вні	54.018168	4/17/2008	3/31/2016
Illinois	Home Nursing	ВНІ	4000353	N/A	Pending renewal
Indiana	Pharmacy	вні	64000943A	2/13/2009	12/31/2015
lowa	Pharmacy	вні	3785	2008	12/31/2015
Kansas	Pharmacy	вні	22-02977	1/19/2012	6/30/2015
Kentucky	Pharmacy	BHI	NJ1477	2/24/2011	6/30/2015
Maryland	Pharmacy	ВНІ	P05613	12/5/2011	5/31/2016
Michigan	Pharmacy	вні	5301009116	5/12/2009	6/30/2016
Minnesota	Pharmacy	BH1	264117	11/17/2010	6/30/2015
Mississippi	Pharmacy	вні	07755/7.1	5/27/2008	12/31/2015
Missouri	Pharmacy	ВНІ	2009000387	1/8/2009	10/31/2015
Montana	Pharmacy	вні	3251	11/23/2011	11/30/2015
Nebraska	Pharmacy	вні	837	7/23/2014	7/23/2015
Nevada	Pharmacy	вні	PH02534	7/20/2009	10/31/2016
New Hampshire	Pharmacy	вні	NR0742	4/21/2010	Pending renewal
New Jersey	Pharmacy	вні	28RS00513100	5/24/1995	6/30/2015
New Mexico	Pharmacy	ВНІ	PH00003517	4/18/2013	Archived
New York	Pharmacy	вні	028415	5/2/2007	4/13/2016
		2	0417/001	1	Π.
North Carolina	Home Care	вні	HC4640	11/12/2013	12/31/2015
North Dakota	Pharmacy	ВНІ	PHAR657	9/22/2010	6/30/2015
Ohio	Pharmacy	ВНІ	NRP.021988800	8/20/2009	3/31/2016
Oklahoma	Pharmacy	вні	99-6160	1/17/2013	1/31/2016
Oregon	Pharmacy	вні	RP-0002654-CS	7/18/2011	3/31/2016
Rhode Island	Pharmacy	вні	PHN10275	4/6/2012	9/30/2015
South Carolina	Pharmacy	ВНІ	13966	5/4/2012	6/30/2015
South Dakota	Pharmacy	BHI	400-0873	8/13/2010	6/30/2015
Tennessee	Pharmacy	BHI	4656	5/29/2009	3/31/2016
Texas	Pharmacy	вні	27129	9/10/2010	9/30/2016
Texas	Home Services	IPM	016696	N/A	3/31/2017
Utah	Pharmacy	вні	8273344-1708	5/23/2012	9/30/2015
Utah	Home Health	IPM	UT000641	6/26/2014	6/30/2015
Vermont	Pharmacy	вні	036.0092254	1/3/2013	7/31/2015
Virginia	Pharmacy	ВНІ	0214001359	10/26/2011	4/30/2016
Virginia	Home Care	IPM	HCO 151239	N/A	7/31/2015
Washington	Pharmacy	ВНІ	PHNR.FO.60280619	6/1/2009	5/31/2016
West Virginia	Pharmacy	ВНІ	MO0560086	3/24/2009	6/30/2015
Wisconsin	Pharmacy	ВНІ	583-43	2/25/2010	5/31/2016
Wyoming	Pharmacy	ВНІ	NR-50253	1/8/2009	6/30/2015



KIM GUADAGNO

New Jersey Office of the Attorney General

Division of Consumer Affairs Board of Pharmacy 124 Halsey Street, 6th Floor, Newark, NJ 07102



STEVE C. LEE Acting Director

Mailing Address: P.O. Box 45013 Newark, NJ 07101 (973) 504-6450

November 13, 2014

Florida Board of Pharmacy 4052 Bald Cypress Way BIN #C-04 Tallahassee, FL 32399-3254

Basic Home Infusion Pharmacy 1401 Valley Road, 4th Floor Wayne, NJ 07470

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by **BASIC HOME INFUSION PHARMACY DEPT.** to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that **BASIC HOME INFUSION PHARMACY DEPT.** was issued a New Jersey registration **28RS00513100** on or about 05/24/1995 and is currently Active and in good standing with an expiration date of 06/30/2015. A review of the Board's files further indicates that public disciplinary action has been taken against this Pharmacy. A certified, true copy of the reportable action(s) filed with the New Jersey Board of Pharmacy is attached.



Very truly yours,
The New Jersey Board of Pharmacy

Anthony Rubinaccio Executive Director



New Jersey Office of the Attorney General

Division of Consumer Affairs Board of Pharmacy 124 Halsey Street, 6th Floor, Newark, NJ 07102



KIMBERLY S. RICKETTS Director

> Mailing Address: P.O. Box 45013 Newark, NJ 07101 (973) 504-6450

January 26, 2006

By Certified and Regular Mail

5131 Roy Putrino, RPIC Basic Home Infusion Pharmacy 17-17 Broadway Fair Lawn, NJ 07410

Re:

Inspection Report # 8-1526A-05-1816

Dear Mr. Putrino:

This letter is to advise you that the New Jersey State Board of Pharmacy (the "Board") has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the board has preliminarily found that you are responsible for the violations noted on Attachment A.

The Board has determined that it will first offer you an opportunity to settle this matter and thereby avoid the initiation of formal disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the acknowledgment below and agree to the following:

- 1. Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of \$7,650.00 (to be paid upon signing of this certification).
- Provide to the Board a Letter of Correction.

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. Any disposition by way of a settlement will be a public record, and will have the same effect as an order of the Board. Any failure to comply with the terms to which you agree will be deemed a violation.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you either personally or with the assistance of an attorney will have an opportunity to respond to the charges and submit evidence and present testimony as may be necessary in order for the Board to make a final determination concerning the charges of unlawful activity.

You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred in the matter.

Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact The Board of Pharmacy, at (973) 504-6450.

The enclosed certification should be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within fifteen (15) days, the Board's settlement offer will be withdrawn, and you will be deemed in default. The allegations against you will be deemed uncontested. The Board will then proceed to schedule the matter for final review and will enter an appropriate order. Once an order has been entered, your failure to pay any penalties may result in further action to suspend or revoke your license.

NEW JERSEY STATE BOARD OF Pharmacy

Joanne Boyer, RPh Executive Director

JB/sk

cc: Marianne Greenwald, Deputy Attorney General

Attachment A

BASIC HOME INFUSION PHARM, 17-17 Broadway, Fair Lawn, NJ 07410, Roy Putrino, Owner/RPh. Bureau File #8-1526A-05-1816. Period 12/16/05.

REFERENCE: Relocation

DETAILS:

Cite	Fine	Description
[13:39-6.3]	\$150.00	One supportive personnel and two pharmacists on duty were not wearing ID tags
[13:39-5.3]	\$50.00	Name of pharmacy does not appear on exterior premises.
[13:39-11.19(d)]	\$1,000.00	The clean room had not been certified as an iso class 6 environment
[13:39-11.20(a)]	\$1,000.00	the ante room has not been certified as an iso class 7 environment.
[13:39-11.7(c)]	Board Review	RPIC and all personnel involved in sterile product compounding have not had their ASEPTIC TECHNIQUE on an annual basis.
[13:39-11.7(a)]	\$2,500.00	Pharmacist in charge and all personnel involved in sterile product compounding shall have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques.
[8:65-6.3]	\$200.00	A Schedule II CDS was transferred to another pharmacy without benefit of a DEA 222 order form.
[13:39-11.13(c)]	\$500.00	Policies and Procedures manual has not been reviewed on a biannual basis.
[13:39-7.19(c)1] [45:14-68(b)9]	\$200.00	Allergies, idiosyncracies or chronic conditions have not been entered into the patient profile system for all persons to whom medication was dispensed. Nor have negative responded received to any such inquiries been recorded. 75% compliance
[13:39-11.15(c)]	\$1,000.00	l g
[13:39-4.14(b)1]	\$50.00	Not all entrances to the pharmacy department are connected to a security device.
Fota!:	87,650.00	



State of New Jersey

OFFICE OF THE ATTORNEY GENERAL DEPARTMENT OF LAW AND PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS BOARD OF PHARMACY 124 HALSEY STREET, 6TH FLOOR, NEWARK NJ Ret# 19034

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address: P.O. Box 45013 Newark, NJ 07101 (973) 504-6450

JAMES E. MCGREEVEY

Governor

July 22, 2004

Roy Putrino, RPIC Basic Home Infusion 17-17 Broadway Fair Lawn NJ 07410

RE: Inspection Report #8-1526A.6

Dear Mr. Putrino:

The Board reviewed your letter of March 18, 2004 in which you offered mitigation offered mitigation concerning the above referenced Inspection Report.

It was the decision of the Board at the May 12, 2004 meeting, to mitigate the following violation(s):

N.J.A.C.13:39-11.5(b)3 for \$1,000.00 and N.J.A.C.13:39-11.14(b)17 from \$250.00 to \$150.00

Since we have received your payment in the amount of \$1,100.00, please submit the remaining balance in the amount of \$1,425.00 along with a letter of corrective action.

Yours truly,

Journa Buyer, RPh
Executive Director

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
4 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101



State of New Jersey

OFFICE OF THE ATTORNEY GENERAL DEPARTMENT OF LAW AND PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS BOARD OF PHARMACY 124 FLALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY Governor

> CERTIFIED MAIL RETURN RECEIPT REQUESTED

PETER C. HARVEY Attorney General RENI ERDOS Director

Mailing Address: P.O. Box 45013 Newark, NJ 07101 (973) 504-6450

February 10, 2004

Roy Putrino, RPIC/Owner Basic Home Infusion 17-17 Broadway Fair Lawn, NJ 07410

> Re: Inspection Report #8-1526A.6 Inspection Date: 9/23/03

Dear Mr. Putrino:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated:

N.J.A.C.13:39-7.13, N.J.A.C.13:39-3.18(e) 10

A total of three containers of medication were discovered to be out-of-date, misbranded, or improperly stored.

- 1. Outdated form 1 day to 4 mos.: two (2) items: Warning
- 2. Outdated from 4 mos. to 1 year: \$25.00

N.J.A.C.13:39-11.7

Not all personnel involved in sterile admixture preparation have practical or academic training in sterile product compounding, clean room technology, laminar flow, technology, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile products and annually thereafter: Specifically:

1. The resume of staff RP John Magalla Jr., Reflects no such training prior to his employment at this pharmacy.

St.000_

24 HALSEY ST., 6TH FL., P.O. BOX 45013 DIVISION OF CONSUMER AFFAIRS **GOARD OF PHARMACY NEWARK, NJ 07101** 2. RP-in-charge Roy Putrino last received such training March 18th 2000. \$250.00

N.J.A.C.13:39-11.10(c)

There is no form which documents the completion of each of the steps of the compound process. \$100

N.J.A.C.13:39-11.1(a)

Prescription labels for sterile admixture products do not have time prepared. \$100

N.J.A.C.13:39-11.14(b)5, N.J.A.C.13:39-11.14(b) 12, N.J.A.C.13:39-11.14(b) 16, N.J.A.C.13:39-11.14(b) 17

Documentation as set forth in 13:39-11.10 is not included in policy and procedure manual. Policy and procedure manual does not have a section for reference materials. There is no topic on patient education in the policy and procedure manual. There is no topic on protocol and procedures to maintain the integrity of the interior work area of the laminar air flow hood.

N,J.A.C.13:39-11.5(b)3

Not all compounding processes representative of all types of manipulations, products, and batches, are being sterile tested and validated at least every 12 months.

N.J.A.C.13:39-11.5(b)4

Surface sampling is not done in the clean room twice annually. \$500

N.J.A.C.13:39-11.18(f)

Floors do not have coving to the sidewall. \$250

N.J.A.C.13:39-11.21(b)

The sink in the anteroom does not have hot running water. \$100

N.J.A.C.8:65-7.5(a), N.J.A.C.8:65-7.8(a)

Accepted and filled prescriptions for Schedule II controlled dangerous substances missing patient address.

Warning

N.J.S.A.45:14-15

A prescription not assigned prescription number. \$25.00

N.J.A.C.13:39-11.11(a) 8

The name of the pharmacy as it appears on prescription label does not compare favorably with the name of the pharmacy as it appears on Board permit. \$25.00

The Board has determined that it will offer you an opportunity to settle this matter and

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
(24 HALSEY ST., 6TH FL., P.O. BOX 45013

thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of \$3,625.00 and provide to the Board a Letter of Corrective Action. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed certification should be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

Joanne Boyer

Executive Director

IR ks

cc: Marianne Greenwald, Deputy Attorney General



State of New Jersey

DEPARTMENT OF LAW AND PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS BOARD OF PHARMACY 124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JOHN J. FARMER, JR. Attorney General

CHRISTINE TODD WHITMAN Governor

> CERTIFIED MAIL RETURN RECEIPT REQUESTED

MARK S. HERE Director

In reply respond t P.O. Box 45013 Newark NJ 0710 (973) 504-6450

September 17, 1999

Ms. Andrea DiFiore, RPIC Basic Home Health Care Pharmacy 17-17 Broadway Fairlawn, NJ 07410

Re:

Inspection Report #8-1526A.4 Inspection Date: 1/29/99-3/10/99

Dear Ms. DiFiore:

This is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminary found that you have violated:

N.J.S.A. 45:14-10

The original certificate of the RP-in-charge was not on display nor present in the pharmacy. \$50.00

N.J.A.C. 13:39-7.11

The metrological equipment, specifically the Class A Balance and Metric Weights, have not been inspected and scaled by the Department of Weights and Measures within a year. Last date of certification was August 13. 1997.

\$50.00

N.J.A.C. 13:39-7.7(a), N.J.A.C. 13:39-3.18(e)

Prescription label does not disclose the name of the current RP-in-charge.

\$100.00 The metrological equipment, specifically the Class A Balance and Metric Weights, have not been

124 HALSEY ST., 6TH FL., P.O. BOX BOARD OF PHARMACY

4.C. 13:39-11,9(5)

Monthly air and surface sampling not performed monthly as required. Warning

N.J.A.C. 13:39-7.7

A current copy of Trissel's Handbook on Injectable Drugs was not present in the pharmacy. \$200.00

The Board has determined that it will first offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of \$400.00
(To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973)504-6450.

The enclosed certification should be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within fifteen (15) days, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

H. Lee Gladstein, RP

Executive Director

HLG:mr

cc: Marianne Greenwald, Deputy Attorney General

Roy C. Putrino, 453 Fairfield Road, Wykoff, NJ 07481

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013

902 KAR 20:275. Mobile health services.

RELATES TO: KRS 216B.010-216B.131, 216B.990

STATUTORY AUTHORITY: KRS 216B.042, 314.011(8), EO 96-862

NECESSITY, FUNCTION, AND CONFORMITY: The administrative regulation establishing standards for mobile health services, 902 KAR 20:270, was found deficient by the Interim Joint Committee on Health and Welfare at its November 15, 1995, meeting. The finding of deficiency resulted from the lack of guidelines to coordinate the relationship between home IV therapy service and home health agencies. Legislation to establish such guidelines was not enacted during the 1996 Regular Session of the General Assembly. Therefore, pursuant to KRS 13A.333(1), 902 KAR 20:270 expired. KRS 216B.042 requires the cabinet to establish standards for health facilities and services, and authorizes it to promulgate administrative regulations. Without an administrative regulation establishing standards for mobile health services, the cabinet would be in violation of the legislative mandate expressed in KRS 216B.042. KRS 13A.333(6) prohibits an administrative body from promulgating an administrative regulation that is identical to or substantially the same as an administrative regulation that has expired. This administrative regulation is not identical to or substantially the same as 902 KAR 20:270, because:

- (1) Only the lack of guidelines to coordinate the relationship between home IV therapy services and home health services was found deficient;
- (2) This administrative regulation includes guidelines to coordinate the relationship between home IV therapy service and home health agencies; and
 - (3) It is required by the legislative mandate of KRS 216B.042.

Executive Order 96-862, effective July 2, 1996, reorganizes the Cabinet for Human Resources and places the Office of Inspector General and its programs under the Cabinet for Health Services.

Section 1. Definitions. (1) "Certified radiation operator" means a person who has been certified pursuant to KRS 211.870 and 902 KAR 105:010 to 105:070 as an operator of sources or radiation.

- (2) "Computed tomography (CT) scanning" means a radiological diagnostic imaging procedure that shows cross sectional images of internal body structures.
- (3) "Governing authority" or "licensee" means the individual, agency, partnership, or corporation, in which the ultimate responsibility and authority for the conduct of the institution is vested.
- (4) "IV therapy" means the administration, by a registered nurse under the supervision of a licensed physician, of various pharmaceutical and nutritional products by intravenous, subcutaneous or epidural routes.
 - (5) "IV therapy service" means pharmaceutical and nursing services, including direct hands-on care, limited to and necessary for the:
 - (a) Preparation, dispensing and delivery of pharmaceutical and nutritional products and equipment; and
 - (b) Related clinical consultation, training, and assessment or care incidental to initial start-up of IV therapy.
 - (6) "License" means an authorization issued by the cabinet for the purpose of operating mobile health services.
 - (7) "Lithotripter" means a noninvasive treatment technique that utilizes shock waves to shatter kidney stones.
- (8) "Magnetic resonance imaging (MRI)" means a diagnostic imaging modality which utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to project images of internal body structures.
- (9) "Other diagnostic and treatment services" means those health services which are determined to require licensure pursuant to KRS 216B.042 as a mobile health service.
- (10) "Qualified anesthesiologist" means a person who is a doctor of medicine or a doctor of osteopathy licensed to practice medicine and surgery and who is board certified or in the process of being certified by the American Board of Anesthesiology or the American Osteopathic Board of Surgery and who otherwise meets the criteria established by the mobile health service's governing authority.
- (11) "Qualified urologist" means a person who is a doctor of medicine or a doctor of osteopathy licensed to practice medicine and surgery and who is board certified or is in the process of being certified by the American Board of Urology or the American Osteopathic Board of Surgery and who otherwise meets criteria established by the mobile health service's governing authority.
 - (12) "Registered nurse" means a nurse who is licensed to engage in registered nursing practice pursuant to KRS 314.041.

Section 2. Scope of Operation and Services. Mobile health services provide medical services in various locations and in some instances utilize a specially equipped vehicle such as a van, trailer or mobile home. These services include mobile diagnostic imaging and examination services, mobile treatment services, and any other medical or dental services provided through the use of a mobile vehicle or performed at various locations.

Section 3. Administration. (1) Licensee.

- (a) The licensee shall be legally responsible for the service and for compliance with federal, state and local laws and regulations pertaining to the operation of the service, limited to the scope of the service's certificate of need.
- (b) The licensee shall establish lines of authority and designate an administrator who will be principally responsible for the daily operation of the service. In the case of a service whose governing authority is comprised of more than one (1) licensed hospital, a separate administrator may be designated from each hospital to serve as the administrator of the service when it is being provided at the hospital where the designee is employed.
 - (2) Policies. There shall be written administrative policies which the service follows covering all aspects of operation, including:
 - (a) A description of organizational structure, staffing and allocation of responsibility and accountability;
 - (b) A description of linkages with inpatient facilities and other providers;
 - (c) Policies and procedures for the guidance and control of personnel performances;
- (d) A written program narrative describing in detail the service(s) offered, methods and protocols for service delivery, qualifications of personnel involved in the delivery of the services, and goals of the service(s);
 - (e) A description of the administrative and patient care records and reports; and
 - (f) Procedures to be followed in the storage, handling and administration of drugs and biologicals.
 - (3) Personnel.
- (a) Medical director. The service shall have a medical director. The medical director shall be a licensed physician or dentist with specialized training and experience in, and responsibility for, all medical aspects of the service. In the case of a service whose governing authority is comprised of more than one (1) licensed hospital, a separate medical director may be designated from each hospital's medical staff to serve as the medical director of the service when it is being provided at the hospital where the physician is on staff. If a service operates only diagnostic examination equipment, and if the service is offered only to licensed hospitals, and if the employees of the service makes no medical assessment of the diagnostic patient data collected, then the service shall be exempt from the requirements of this paragraph.
- (b) The service shall employ, or provide for through a written contractual agreement, sufficient number of qualified personnel to provide effective patient care and all other related services. The licensee shall provide written personnel policies which shall be available to all employees, reviewed on an annual basis, and revised as necessary. If the staff-to-patient ratio does not meet the needs of the patients, the Division of Licensing and Regulation shall determine and inform the program administrator in writing how many additional personnel are to be added and of what job classification, and shall give the basis for this determination.

- (c) There shall be a written job description for each position which shall be reviewed and revised as necessary.
- (d) There shall be an employee health program for mutual protection of employees and patients including provisions for preemployment and periodic health examination, tuberculin test, and other appropriate tests.
 - (e) Current personnel records shall be maintained for each employee which include the following:
 - 1. Name, address and Social Security number;
 - 2. Evidence of current registration, certification or licensure of personnel;
 - 3. Records of training and experience; and
 - 4. Records of performance evaluation.
- (4) In-service training. All personnel shall participate in ongoing in-service training programs relating to their respective job activities including thorough job orientation for new employees.
 - (5) Medical records.
 - (a) The service shall maintain medical records which contain at least the following:
 - 1. Medical and social history relevant to the service(s) provided, including data obtainable from other providers;
 - 2. Names of referring physician, if any, and physician's orders for special diagnostic services such as x-ray or CT scans;
- 3. Description of each medical visit or contact, to include condition or reason necessitating visit or contact, assessment diagnosis, services provided, medications and treatments prescribed, and disposition made;
 - 4. Reports of all physical examinations, laboratory, x-ray, and other test findings relevant to the service(s) provided; and
- 5. Documentation of all referrals made, including reason for referral, to whom patient was referred, and any information obtained from referral source.
 - (b) Confidentiality of all patient records shall be maintained at all times.
- (c) Transfer of records. The service shall establish systematic procedures to assist in continuity of care where the patient moves to another source of care, and the service shall, upon proper release, transfer medical records or an abstract thereof when requested.
- (d) Retention of records. After patient's death or discharge the completed medical record shall be placed in an inactive file and retained for five (5) years or in case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is longer. Mammography and other radiology records shall be retained in accordance with federal requirements.
 - (e) A specific location shall be designated by the mobile health service for the maintenance and storage of the service's medical records.
- (f) Provisions for storage of medical records in the event the mobile health service ceases to operate because of disaster, or for any other reason. The licensee shall safeguard the record and its content against loss, defacement and tampering.

Section 4. Vehicle Requirements. (1) All vehicles used in the provision of a health service, as provided by the service's certificate of need, shall be kept, in optimum order with clean interiors and equipment.

- (2) The following standards shall apply only to those vehicles which the patient enters.
- (a) There shall be adequate heating and air-conditioning capability in both the driver and patient compartments.
- (b) There shall be a minimum of two (2) potential power sources for the vehicle. To insure an immediately available source of power in the event of a power failure, one (1) must be self-contained on the vehicle. The other source must be an exterior source of power hookup.
- (c) The vehicle shall be accessible to users with disabilities either through the use of a wheelchair lift or a ramp which complies with applicable American National Standards Institute (ANSI) requirements.
 - (d) The vehicle shall have adequate and safe space for staff and examination procedures, as determined by the cabinet.
- (e) Equipment. Vehicles used in the provision of a health service, as provided by the service's certificate of need, shall have the following essential equipment:
 - 1. One (1) five (5) pound dry chemical fire extinguisher;
 - 2. One (1) first aid kit;
 - 3. Suction apparatus;
 - 4. Oxygen equipment (portable) including:
 - a. One (1) "D" size oxygen cylinder;
 - b. One (1) pressure gauge and flow rate regulator;
 - c. Adaptor and tubing; and
 - d. Transparent masks for adults and children. Nasal cannulas may be substituted.
- (f) Personnel. Each mobile health service vehicle shall at a minimum be staffed by one (1) person, who may also be the driver of the vehicle, who shall have the following qualifications:
- 1. Red Cross Advanced and Emergency Care Certification, each with supplemental CPR instruction certified by the American Red Cross or the American Heart Association; or
 - 2. EMT-first responder certification; or
 - 3. EMT-A certification; or
 - 4. Licensure as a registered nurse, physician or dentist.

Section 5. Requirements for Provision of Services. A licensed mobile health service shall comply with the requirements listed in Sections 3, 4, and 6 of this administrative regulation, the service's program narrative, and the additional requirements of this section which relate to the particular service(s) offered by the licensee.

- (1) Diagnostic services. Diagnostic services are those services which are performed to ascertain and assess an individual's physical health condition.
- (a) Diagnostic services, except for mammography services, shall be performed only on the order of a physician or advanced practice registered nurse as authorized in KRS 314.011(8).
- (b) The service shall prepare a record for each patient to include the date of the procedure, name of the patient, description of the procedures ordered and performed, the referring physician, the name of the person performing the procedure, the date and the name of the physician to whom the results were sent.
 - (c) Diagnostic imaging services.
- 1. Diagnostic imaging services are those services which produce an image, either through film or computer generated video, of the internal structures of a patient. These services include:
 - a. X-ray;
 - b. MRI;
 - c. CT scanning;
 - d. Ultrasound;
 - e. Mammography;
 - f. Fluoroscopy; and
 - g. Other modalities using directed energy to gain statistical, physiological or biological diagnostic imaging information.

- 2. Any mobile health service which provides diagnostic imaging services shall comply with the following:
- a. Equipment used for direct patient care shall be fully approved by the Federal Food and Drug Administration (FDA) for clinical use;
- b. There shall be a written preventive maintenance program which the service follows to ensure that imaging equipment is operative, properly calibrated, and shielded to protect the operator, patient, environment, and the integrity of the images produced. Recalibration of radiation producing and nonradiation producing instrumentation shall occur at least every six (6) months by biomedical service personnel and radiation producing instrumentation shall be recalibrated annually by a consulting health physicist.
- c. Diagnostic imaging services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of the specific imaging technique for diagnostic purposes;
- d. Imaging services shall have a current license or registration pursuant to applicable Kentucky statutes and any administrative regulations promulgated thereunder;
- e. All Personnel engaged in the operation of imaging equipment shall be currently licensed or certified in accordance with applicable Kentucky statutes and administrative regulations;
 - f. There shall be a written training plan for personnel in the safe and proper usage of the mobile imaging equipment and system;
- g. There shall be a physician's signed order which specifies the reason the procedure is required, the area of the body to be examined, and a statement concerning the condition of the patient which indicates why mobile imaging services are necessary; and
- h. There shall be sufficiently trained on-duty personnel with adequate equipment to provide emergency resuscitation services in the event of a patient emergency.
 - (d) Other diagnostic services.
- 1. Other diagnostic services are those services which are provided through the use of diagnostic equipment, and physical examination. These services include:
 - a. Electrocardiogram services;
 - b. Electroencephalogram services;
 - c. Holter monitor services;
 - d. Disability determination services;
 - e. Pulmonary function services;
 - f. Aphresis services;
 - g. Blood gas analysis services;
 - h. Echosonogrophy services; and
 - i. Doppler services.
 - 2. Equipment used for direct patient care shall comply with the following:
- a. The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative and properly calibrated;
- b. All Personnel engaged in the operation of diagnostic equipment shall have adequate training and be currently licensed or certified in accordance with applicable Kentucky statutes and administrative regulations; and
 - c. There shall be a written training plan for the adequate training of personnel in the safe and proper usage of the equipment.
- 3. Physical examination services shall be nonabusive and provided in a manner which ensures the greatest amount of safety and security for the patient.
 - a. Protocols for diagnostic examinations shall be developed by the medical director.
- b. Personnel performing physical examinations shall have adequate training and be currently licensed or certified in accordance with applicable Kentucky statutes and administrative regulations.
 - c. Personnel performing physical examinations shall be limited by the relevant scope of practice of Kentucky licensure.
- (2) Treatment services. Treatment services are those services provided to an individual who, because of a physical health condition, is in need of medical assistance for the attainment of their maximum level of physical function.
- (a) Mobile health clinic. A mobile health clinic is a health service providing both diagnostic and treatment services through the use of a mobile vehicle. A mobile health clinic may provide a wide range of diagnostic and treatment services on an outpatient basis for a variety of physical health conditions.
- 1. Policies. The licensee shall develop patient care policies with the advice of a group of professional personnel that includes one (1) or more physicians and one (1) or more advanced practice registered nurses. At least one (1) member shall not be a member of the mobile health clinic staff. The policies shall include:
 - a. A description of the services the mobile health clinic provides directly and those provided through agreement;
- b. Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, and the maintenance of health records; and
 - c. Procedures for review and evaluation of the services provided by the clinic at least annually.
- 2. Personnel. The mobile health clinic shall have a staff that includes at least one (1) physician and at least one (1) advanced practice registered nurse. The clinic shall employ such other staff or ancillary personnel that are necessary to provide the services essential to the clinic's operation.
 - a. The physician shall:
- (i) Be responsible for all medical aspects of the clinic and shall provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311. In addition, the physician shall provide medical direction, supervision, and consultation to the staff;
- (ii) In conjunction with the advanced practice registered nurse(s), participate in developing, executing, and periodically reviewing the mobile health clinic's written policies and services:
- (iii) Periodically review the mobile health clinic's patient records, provide medical orders, and provide medical care services to patients of the mobile health clinic; and
- (iv) Be present for consultation weekly, and be available within one (1) hour, through direct telecommunication for consultation, assistance with medical emergencies, or patient referral.
 - b. The advanced practice registered nurse shall:
 - (i) Participate in the development, execution and periodic review of the written policies governing the services the mobile health clinic provides;
 - (ii) Participate with the physician in periodic review of patient health records;
- (iii) Provide services in accordance with mobile health clinic policies, established protocols, the Nurse Practice Act (KRS Chapter 314), and with administrative regulations promulgated thereunder;
 - (iv) Arrange for, or refer patients to needed services not provided at the mobile health clinic; and
 - (v) Assure that adequate patient health records are maintained and transferred when patients are referred.
 - 3. The mobile health clinic shall have linkage agreements or arrangements with each of the following:
 - a. Inpatient hospital care;
 - b. Physician services in a hospital, patient's home, or long-term care facility;
 - c. Additional and specialized diagnostic and laboratory services that are not available at the mobile health clinic;
 - d. Home health agency;

- e. Emergency medical services;
- f. Pharmacy services; and
- g. Local health department.
- 4. The mobile health clinic shall carry out, or arrange for an annual evaluation of its total program, shall consider the findings of the evaluation, and take corrective action, if necessary. The evaluation shall include:
 - a. The utilization of clinic services including at least the number of patients served and the volume of services;
 - b. A representative sample of both active and closed clinical records; and
 - c. The mobile health clinic's health care policies.
- 5. The mobile health clinic shall develop and maintain written protocols, i.e., standing orders, rules of practice, and medical directives, which apply to services provided by the clinic and which explicitly direct the step-by-step collection of subjective and objective data from the patient. The protocols shall further direct data analysis, direct explicit medical action depending upon the data collected, and include rationale for each decision made. The protocols shall be signed by the staff physician.
- 6. The Mobile health clinic staff shall furnish those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.
 - 7. The mobile health clinic shall provide basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:
 - a. Chemical examinations of urine by stick or tablet methods or both (including urine ketones);
 - b. Microscopic examinations of urine sediment;
 - c. Hemoglobin or hematocrit;
 - d. Blood sugar;
 - e. Gram stain;
 - f. Examination of stool specimens for occult blood;
 - g. Pregnancy tests;
 - h. Primary culturing for transmittal to a hospital laboratory or licensed laboratory; and
 - i. Test for pinworms.
- 8. The mobile health clinic shall provide medical emergency procedures as a first response to common life-threatening injuries and acute illness, and have available the drugs and biologicals commonly used in lifesaving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.
- 9. The clinic shall post in a conspicuous area at the entrance, visible from the outside of the clinic, the hours that emergency medical services will be available in the clinic, the clinic's next scheduled visit, and where emergency medical services not provided by the clinic can be obtained during and after the clinic's regular scheduled visits and hours of operation.
- (b) Mobile dental clinic. A mobile dental clinic is a health service providing both diagnostic and dental treatment services at different locations through the use of a mobile vehicle or equipment.
- 1. Policies. The licensee shall develop patient care policies with the advice of a group of professional personnel that includes at least one (1) licensed dentist. These policies shall include:
 - a. Guidelines which identify the dental problems which may not be performed in the mobile unit, and provisions for patient referral;
 - b. Guidelines for the review and evaluation of the services provided by the clinic at least annually, and
 - c. Guidelines for procedures to be followed in the event a patient has a medical emergency.
 - 2. Personnel. The mobile dental clinic shall have a staff that includes at least one (1) licensed dentist and at least one (1) dental assistant.
 - a. The dentist shall:
- (i) Be responsible for all aspects of patient care in accordance with KRS Chapter 313 and any administrative regulations promulgated thereunder;
 - (ii) Be present in the clinic at all times that a patient is receiving dental care; and
 - (iii) Provide direct supervision to all staff involved in the delivery of services.
 - b. The dental assistant shall:
- (i) Provide services in accordance with the mobile dental clinic policies and established protocols, KRS Chapter 313, and any administrative regulations promulgated thereunder; and
 - (ii) Provide services only under the direct supervision of a licensed dentist.
 - 3. Equipment. The mobile dental clinics shall have the following equipment:
 - a. X-ray units;
 - b. Sterilizer;
 - c. High-speed suction;
 - d. Dental lights; and
 - e. Emergency kit with the following drug types:
 - (i) Antiallergenic;
 - (ii) Vasodilators;
 - (iii) Anticonvulsives; and
 - (iv) Vasopressors.
- (c) Mobile lithotripter service. A mobile lithotripter service is a health service which provides for a noninvasive technique for removing kidney or ureteral stones through the use of a lithotripter at various hospital locations.
 - 1. Mobile lithotripter services may only be delivered on the grounds of the hospital utilizing the mobile lithotripter service.
 - 2. Lithotripsy services shall be performed only on the order of a physician.
- 3. Lithotripsy services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of lithotripsy treatment.
- 4. The service shall prepare a record for each patient to include the date of the procedure, name of the patient, description of the procedures ordered and performed, the referring physician, and the name of the person performing the procedure.
- 5. There shall be a physician's signed order which specifies the reason the procedure is required, the area of the body to be exposed, and the anticipated outcome of treatment.
- 6. Policies. A mobile lithotripter service shall develop patient care policies with the advice of a group of professional personnel that includes at least one (1) qualified urologist and one (1) qualified anesthetist. At least one (1) member shall not be a member of the mobile lithotripter service staff. The policies shall include:
 - a. A description of how a patient will be transported between the hospital and the mobile lithotripter service;
 - b. Procedures to be followed in the event a patient has a medical emergency;
 - c. Guidelines for the review and evaluation of the service on an annual basis; and
 - d. Policies and protocols governing the utilization and responsibilities of hospital staff in the delivery of lithotripter services.
 - 7. Personnel. The mobile lithotripter service shall employ at least one (1) lithotripter technician, and shall employ or make arrangements with the

hospital utilizing the service for at least one (1) registered nurse, one (1) qualified urologist to be present in the unit during the delivery of lithotripsy services, and one (1) qualified anesthetist to be available for procedures requiring anesthesia.

- 8. Lithotripsy equipment used for direct patient care shall comply with the following:
- a. Lithotripsy equipment shall be fully approved by the Federal Food and Drug Administration (FDA) for clinical use;
- b. The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative, properly calibrated, properly shielded, and safe for the patient, operator, and environment;
- c. All Personnel engaged in the operation of diagnostic equipment shall have adequate training and be currently licensed, certified or registered in accordance with applicable Kentucky statutes and administrative regulations; and
 - d. There shall be a written training plan for the adequate training of personnel in the safe and proper usage of the equipment; and
- e. There shall be sufficiently trained on-duty personnel with adequate equipment to provide emergency resuscitation in the event of a patient emergency.
 - (d) Other treatment services, including IV therapy services, shall be performed only on the order of a physician.
- 1. IV therapy shall only be performed by a registered nurse and shall be limited to nursing services which are required for the initial start-up of an IV therapy program.
- 2. If nursing services are required which exceed the initial start-up of IV therapy, they shall be provided by an appropriately licensed agency to provide care under a physician's plan of care.
 - 3. All services provided shall be under the supervision of a licensed physician.
- 4. Policies. The licensee shall develop patient care policies with the advice of a group of professional personnel that includes one (1) or more physician(s) and one (1) or more registered nurse(s). At least one (1) member shall not be a member of the service's staff. The policies shall include:
 - a. A description of the services provided;
 - b. A requirement to inform patients of other in-home services which can be provided only by other appropriately licensed agencies;
- c. A requirement for a written common plan for treatment and coordination of treatment with other licensed health care providers servicing the patient, and immediate verbal communication between providers of revisions in the common plan shall be documented in the plan of treatment;
- d. Guidelines for the medical management of health problems which include the conditions requiring medical consultation or patient referral, and the maintenance of health records;
 - e. Procedures for review and evaluation of the services provided at least annually, and
 - f. Guidelines for patient and environment assessment.
- 5. Personnel. The service shall have a staff that includes at least one (1) registered nurse. The service shall employ such other staff or ancillary personnel that are necessary and essential to the service's operation. The registered nurse shall:
 - a. Participate in the development, execution and period review of the written policies governing the services provided;
 - b. Participate with the physician in periodic review of patient health records;
- c. Provide services in accordance with established policies, protocols, the Nurse Practice Act (KRS Chapter 314), and with administrative regulations promulgated thereunder;
 - (i) Arrange for or refer patients to needed services that cannot be provided by the service; and
 - (ii) Assure that adequate patient health records are maintained and transferred when patients are referred.
 - 6. In-service training programs shall include instruction in:
 - a. Use of equipment;
 - b. Side effects and precautions of drugs and biologicals; and
 - c. Infection control measures.
- 7. The service shall carry out, or arrange for an annual evaluation of its total program, shall consider the findings of the evaluation, and take corrective action, if necessary. The evaluation shall include:
 - a. The utilization of the service including at least the number of patients served and the volume of services;
 - b. A representative sample of both active and closed records; and
 - c. The service's health care policies.
- Section 6. Waste Processing. (1) Sharp wastes, such as broken glass, scalpel blades, and hypodermic needles, shall be segregated from other wastes and aggregated in rigid disposable containers immediately after use. Needles and syringes shall not be cut, dismantled, or destroyed after use, but shall be placed intact into a rigid container. The rigid containers of sharp wastes shall either be incinerated or disposed of in a sanitary landfill approved pursuant to 401 KAR 47:080.
- (2) The mobile health service shall establish a written policy for the handling and disposal of all pathological and microbiologic laboratory waste. Any incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:020 or 401 KAR 61:010.
- (a) Pathological and microbiologic laboratory waste shall be placed in double impervious plastic bags and each bag shall be two (2) mils in thickness. A bag, when full, shall not exceed twenty-five (25) pounds. All bags shall be securely closed and a tag, which reads "INFECTIOUS WASTE" and identifies the mobile health service from which the waste is being removed, shall be attached to the bag in a conspicuous manner. These wastes shall be sterilized before disposal or be disposed of by incineration if they are combustible.
 - (b) All unpreserved tissue specimens shall be incinerated off site.
 - (3) The following liquids shall be disposed of by incineration or by sanitary sewer:
 - (a) Blood;
 - (b) Vaginal or cervical secretions or exudates;
 - (c) Semen;
 - (d) Cerebrospinal, synovial, pleurol, pericardial, peritoneal or amniotic fluids;
 - (e) Saliva in dental procedures;
 - (f) Fluids visibly contaminated with blood; and
- (g) Mixed fluids where any of the above may be involved. (23 Ky.R. 2645; Am. 2999; eff. 1-15-1997; TAm eff. 3-11-2011; TAm eff. 12-10-2012.)



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 **www.tn.gov/hsda** Phone: 615-741-2364 Fax: 615-741-9884

June 1, 2015

Melissa Hess, Director of Nursing Implanted Pump Management 200 Prosperity Place, #102 Knoxville, TN 37923

RE: Implanted Pump Management, LLC - Certificate of Need CN1407-027

The establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The parent office will be located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932. There are no branch offices proposed for this project. The service area includes all 95 counties in Tennessee. The estimated project cost is \$13,038.00.

Dear Ms. Hess:

This is to notify you that the referenced application is scheduled to be acted upon by the Agency at its next monthly meeting in Nashville on Wednesday, June 24, 2015 beginning at 8:30 A.M. The meeting will be held at the following location:

Legislative Plaza
Room 12
Sixth Avenue North & Union Street
Nashville, TN

Please be present and prepared to make a brief presentation and to respond to any questions regarding the application. Your presentation should address the following:

- Why the project is needed to provide necessary health care in the service area;
- How it can be economically accomplished and maintained; and,
- Its contribution to the orderly development of adequate and effective health care facilities and/or services.

In its review of the project, the Agency will weigh and consider the health care needs of consumers, particularly women, racial and ethnic minorities, TennCare or Medicaid recipients and low income groups. The applicant's current and future commitment to TennCare and any contractual agreements should be disclosed if applicable to the type facility or service sought.

Should you desire that Agency members receive information that has not been previously submitted, please forward 14 copies of the information to this office by noon on **June 10, 2015.**

Meeting procedure information is enclosed for your review. Please call if you have any questions.

Sincerely,

Melanie M. Hill Executive Director

Enclosure

HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING MARCH 25, 2015 APPLICATION SUMMARY

NAME OF PROJECT:

Implanted Pump Management, LLC

PROJECT NUMBER:

CN1407-027

ADDRESS:

200 Prosperity Place, Suite 102

Knoxville, (Knox County), Tennessee 37923

LEGAL OWNER:

Implanted Pump Management, LLC

1401 Valley Road

Wayne, New Jersey 07470

OPERATING ENTITY:

Not Applicable

CONTACT PERSON:

Melissa Hess, Director of Nursing

Implanted Pump Management, LLC

200 Prosperity Place, Suite 102 Knoxville, Tennessee 37923

(201) 475-9635

DATE FILED:

July 3, 2014

PROJECT COST:

\$13,038

FINANCING:

Cash Reserves

PURPOSE FOR FILING: Establishment of a home care organization and the initiation of specialized home health services limited

to intrathecal pump services.

DESCRIPTION:

Implanted Pump Management, LLC (IPM) is requesting approval to establish a home care organization and provide specialized skilled nursing services for patients with surgically implanted intrathecal pumps under physician's orders. The applicant's proposed specialized home health service will be contractually supported by Basic Home Infusion Pharmacy located at 1401 Valley Road in Wayne, New Jersey; Intrathecal Compounding Specialists, LLC (ICS) located at 206A Jacob's Run in Scott, Louisiana; and possibly other qualified pharmacies to

be selected by the applicant as necessary. Both named pharmacies hold active Tennessee licenses issued by the Tennessee Department of Health. The applicant states that the pharmacies will be contracted to provide medication compounding, processing of physician orders, medication dose titrations and changes, and consultation with the appropriate dispensing physician, patient and IPM clinical staff. An overview of the nature and scope of the services provided by the applicant and the contracted pharmacy (s) is summarized on pages 10 and 11 of the application, pages 22-23 of Supplemental 1 and page 8 of Supplemental 2.

The applicant proposes serving all 95 Tennessee Counties from a home office located at 200 Prosperity Place, Suite 102 in Knoxville (Knox County), Tennessee.

Important Note to Agency Members: Following HSDA completeness review ending September 2014, the application was submitted to TDH for mandatory 60 day licensing agency review in accordance with HSDA Rules. Subsequently, John Dreyzehner, MD, MPH, Commissioner, Tennessee Department of Health, submitted a letter on November 24, 2014 to Melanie Hill, Executive Director, HSDA, requesting that the Agency's Board defer hearing the application in December 2014 by granting an additional 90 days before hearing the application in order to finalize its review of the project. HSDA approved the request and placed the application on the agenda for the March 25, 2015 Agency meeting. Dr. Dreyzehner's letter follows this summary.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

- 1. The need for home health agencies/services shall be determined on a county by county basis.
- 2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.
 - The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
- 3. Using recognized population sources, projections for four years into the future will be used.
- 4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

The applicant states that the specialized nature of the proposed skilled nursing service and the lack of comparable utilization data from existing agencies impact the ability to provide an estimate of need for specialty infusion therapy services. Following Steps 1-4 above, the Department of Health report that is based on 2013 "Final" data indicates that 102,503 residents of the applicant's proposed 95 county service area will need home health care in 2018; however approximately 184,157 patients are projected to be served in 2018 by existing home health organizations resulting in a net excess or surplus of (81,654).

It appears that this application does <u>not</u> meet the criterion.

5. Documentation from referral sources:

a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

During initial staff review of the application, the applicant provided letters of support in the application from two patients that currently have implanted intrathecal pumps and 3 medical pump vendor representatives (pages 67-72 of application). The applicant also provided letters from a physician member of Neurosurgical Associates in Nashville and a member of Comprehensive Pain Specialists in Hendersonville (see 9/11 and 9/19 letters in Additional Information to Supplemental 4). Although the 2 physicians mention the need for the proposed service, no indication is given regarding the potential number of referrals.

Since the applicant is requesting a 95 county service area, it appears that this criterion <u>has not been met.</u>

b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant projects approximately 1,440 total visits in Year 1 for approximately 120 intrathecal pump patients increasing to 2,880 total visits in Year 2 for 240 patients (note: using estimates from existing intrathecal pump vendors, the applicant states that approximately 300 intrathecal pumps are currently in use in Tennessee). It expects to receive

referrals from physicians who initiate intrathecal implanted pump therapy such as neurosurgeons, other surgeons that may implant the pumps, and physicians with specialties in pain management or neurology. Clarification about the sources of referrals is addressed on page 22, Supplemental 2. The applicant notes that patients requiring skilled nursing services for assistance with infusion pump medication refills, titrations, and changes in medical condition would be candidates for referrals by physicians. However, as previously noted, the 2 physician referral letters did not specify the number of potential referrals.

It appears this criterion has been met.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided letters on pages 71 and 72 of the application from two individuals residing in Tennessee (Gainesboro and Lebanon) that state a home care option would be the best for them and their families. As noted, letters were provided by 2 physicians who practice in the Middle Tennessee area in Supplemental 4.

Since the applicant is requesting a 95-county service area, it appears that this criterion has not been met.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant describes the specialized and unique nature and scope of the proposed services in Section B, pages 11 and 12 and Section C, pages 20-24 of the application. ICD-9 codes and key CPT codes that illustrate same were submitted with Supplemental 3. Note: potential errors such as incorrect pump programming and incorrect medication dosage are discussed in more detail on pages 8 and 24 of Supplemental 1.

The applicant stated that Camellia Home Health (TN license # 0144) has the ability to provide skilled nursing services to intrathecal implanted pump patients in its 28 county East Tennessee service area. However, the applicant maintains that the agency's Director of Nursing states that Camellia has not yet provided intrathecal pump services to any of its Tennessee patients (page 2, Supplemental 4).

IPM's proposed specialty infusion services would be provided by trained nursing staff that must complete and pass a credentialed nurse training program. Based on all of the factors above, the applicant maintains that the provision of skilled nursing services for intrathecal pump patients is unique and does not appear to be provided by other existing home health agencies in Tennessee.

It appears this criterion has been met.

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.

The applicant projects an average gross charge of \$200 per skilled nursing visit based on 1,440 total projected visits in Year 1 and 2,880 total visits in Year 2 of the project. Note: the average charge excludes medications provided by the contracted pharmacy that will do its own billing for its services.

Per the response provided on page 19 of Supplemental 1, the applicant states that average cost is \$100.00 per visit. This appears to be relatively consistent with the \$105.24 cost per visit in Year 1 decreasing to approximately \$70.73 per visit in Year 2per the budgeted operating expenses in the Projected Data Chart of the application. Although there are no known agencies with similar services for comparison, the applicant notes that typical reimbursement by commercial plans ranges from \$150-\$250 per visit. The applicant also notes that Medicare does not cover its proposed skilled nursing services for home infusion services.

It appears this criterion has been met.

b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant expects to provide 1,440 total visits for approximately 120 patients per day in Year 1 increasing to 2,880 total visits for 240 patients in Year 2, based on 12 visits per intrathecal pump patient per year. As noted, it appears that there is an average cost of approximately \$105.24 per visit in Year 1 (note: this amount also equates to \$1,262.82 per patient in Year 1).

It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

Implanted Pump Management, LLC an existing, New Jersey Limited Liability Corporation formed in February 2012 and registered in Tennessee in October 2013, seeks approval to establish a home health organization and provide skilled nursing services limited to patients with surgically implanted intrathecal infusion therapy pumps. The applicant states that it also plans to provide services to implanted pump patients in other states in the near future, including Florida, Utah and New Jersey, subject to meeting appropriate licensure requirements. IPM's proposed nursing services will be provided to patients in their home under physician ordered plans of care. The proposed home health agency will be located in approximately 80 square feet of leased office space at 200 Prosperity Place, Suite 102 in Knoxville, Tennessee.

The applicant's nursing team will consist of 2-3 fulltime equivalent registered nurses in Year 1 that will serve approximately 120 patients in their homes statewide in all 95 Tennessee counties. IPM states that its nursing staff model is based on the following: 1) a staff ratio of one nurse to 40 patients, 2) a geographical coverage area within a 180-mile radius of the nurse's home address, and 3) capability of implementing any physician orders within 48 hours. The applicant will also provide a call center to expand contact with patients and physicians on a 24/7 basis. Additionally, patient physicians will have 24/7 secure access to their patient's clinical information using IPM's proprietary web portal. Melissa Hess, RN, the contact for the Certificate of Need application, will serve as the proposed agency's administrator.

As noted during review of the application by HSDA and the Tennessee Department of Health (TDH), the applicant has plans to contract with 2 specialty compounding pharmacies that are presently licensed by TDH to support the proposed intrathecal pump service in Tennessee. These include 1) Basic Home Infusion of Wayne, New Jersey, whose majority owner, Roy Putrino, is also the single member of the applicant LLC (license # 4656, issued 5/2009, expires 3/2016), and 2) Intrathecal Compounding Specialists (ICS) of Scott, Louisiana, which is not related by ownership to the applicant (license # 4485, issued 2/2008, expires 2/2016). Additional information about the Louisiana compounding pharmacy is provided on page 4 of supplemental 1 and attachment 4 of Supplemental 2. A draft contract between the applicant and ICS that identifies the responsibilities of

the parties is provided with the attachments to Supplemental 3. As indicated in the TDH summary, e-mail correspondence from the applicant addressed questions pertaining to the licensure status of both pharmacies, including status of corrective action in response to civil penalties, sanctions or judgments.

The payor types of home health patients to be served by the applicant will be commercial insurance that provide home care benefits or self-pay patients. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid. Although the applicant states that it has no plans to provide charity care, a small amount averaging approximately \$1,500 per year is budgeted in the Projected Data Chart for these patients.

The applicant maintains that its proposed in-home skilled nursing service activities required in connection with implanted pump infusion therapy patients focuses on serving as an "extension" to patient physicians to assist in facilitating the highest possible therapy outcomes. Key activities include patient/family education; medication administration for pump refills in accordance with physician orders; comprehensive nursing consisting of vital signs, determination of pain or spasticity level; complete head to toe assessment; and a telemetry reading of the pump in accordance with practice guidelines. These services will be provided by the applicant's registered nurse employees who must complete IPM's comprehensive nursing education program prior to being assigned a patient caseload. IPM's nursing staff roles and responsibilities are addressed on page 23 of the application. Additional clarification was provided on pages 1-2 of Supplemental 1, pages 3-7 of Supplemental 2 and pages 25-30 of the TDH questions in Exhibit 2 of Supplemental 3 (note: a copy of IPM's nursing training module was submitted with Supplemental 3).

The contracted compounding pharmacy is expected to be actively accredited and follow all state and federal regulations in regards to intrathecal pump medications and narcotics. The pharmacy will receive and process the physician orders then compound, package and ship the medication with a copy of the signed physician order to the applicant's assigned registered nurse (RN). The IPM staff nurse will then transport the medication to ensure temperature control and safety and will administer the medication to the patient in his/her home in accordance with signed physician orders. Types of infusion products to be administered include refills of intrathecal pump pain medications under physician orders for patients with cancer pain, multiple sclerosis or cerebral palsy. (Sources: page 22, Supplemental 1 and page 4, Supplemental 3)

Note to Agency Members: the above is a brief summary of the nature and scope of the proposed in-home skilled nursing service for infusion therapy patients. For more detailed descriptions about the nature and scope of services, including measures

taken to reduce the risks associated with these types of patients, please see the HSDA and TDH staff questions for Items 5.A - 5.L on pages 1-6 of Supplemental 1, Items 4.A-4.J on pages 3-7 of Supplemental 2 and Exhibit 1 and Exhibit 2 of Supplemental 3.

A description of patients with demonstrated needs for implanted pump infusion nursing services in the home that may otherwise be unavailable from other home health agencies is summarized as follows:

Implanted Intrathecal Pump Infusion Therapy - this highly specialized service is given to a very narrow and complex range of patients who have failed traditional therapy for severe or chronic pain and now rely on implanted drug delivery systems for their treatment. Types of patient conditions include pain secondary to cancer, multiple sclerosis, traumatic brain injury, head trauma, paralysis or stroke. Carefully selected by their physicians, these patients will have a specialized pump implanted in the intrathecal space surrounding the spinal cord during a surgical procedure in an inpatient or outpatient setting and their medication regimen started. Implanted pump infusion therapy may be appropriate for patients who have the care and resources available to manage potential risks such as infection, narcotic withdrawal, drug compounding errors and pump programming errors. Typical patient diagnoses include Chronic Pain Syndrome, Complex Regional Pain Syndrome, Multiple Sclerosis, Cerebral Palsy, Abnormal Involuntary Movement (Spasticity) and Traumatic Brain Injury. (For further detail regarding the ICD-9 codes that apply to these patients please see page 9. Supplemental 2).

<u>Ownership</u>

The applicant is a New Jersey limited liability corporation first formed in 2012 with one member, Mr. Roy Putrino, a licensed pharmacist located at 1401 Valley Road in Wayne, New Jersey. Mr. Putrino also has ownership interests in Basic Home Infusion Pharmacy (BHI), formerly Basic Home Care. BHI is one of the two pharmacies that the applicant intends to contract with for the proposed inhome intrathecal pump skilled nursing service.

- As described in more detail in the TDH summary, BHI holds an active non-resident Tennessee pharmacy license that was first issued by TDH in May 2009. BHI is also a licensed pharmacy in several other states, including Illinois, Colorado, Indiana, New Jersey and Indiana (note: please see questions to the applicant in the TDH summary pertaining to concerns and questions regarding BHI's prior history).
- The applicant expects to begin serving intrathecal pump patients in other states, including Florida, Utah and New Jersey, subject to state home health licensure requirements and related requirements or mandates.

- IPM holds a provisional home health license in Utah and is pending licensure in Florida.
- Per the applicant, it appears that IPM is exempt from home health licensure in New Jersey on the basis of providing one single service.
- An executive level organizational chart is provided on page 47 of the application.

Facility Information

- The parent office of the proposed project will be in approximately 80 square feet of leased space in an existing office building in downtown Knoxville at 200 Prosperity Place.
- The office will be used solely for administrative support purposes as a repository for home health service policies and procedures, personnel records and other required documentation.
- There is no construction, renovation or modification required to implement the proposed project.
- Per Item 4, page 10 of Supplemental 1, branch offices will not be used based on the specialized nature of the proposed service.

Project Need

- Lack of agencies that provide in-home skilled nursing care to intrathecal pump patients.
- Physicians requesting availability of in-home supportive nursing care model for their intrathecal pump patients.
- Need for specialized agency(s) that can serve as extension of physicians by providing nursing care to patients in their home and providing accurate and timely clinical information through secure means.
- Difficulty by patients to travel to physician for pump refills and office visits, especially patients with limited mobility or who are homebound.
- Need for accurate, reliable and timely information systems support to maintain patient medical record and facilitate communication with physicians through secure means. IPM's electronic medical record system and secure web portal for attending physicians appears to be innovative initiatives in addressing this need.
- As noted in this application and other similar projects for specialized infusion therapy services, traditional home health agencies do not typically provide in-home skilled nursing care for patients with surgically implanted intrathecal infusion pumps. Please note the comparison in the table below.

Comparison of Applicant to Other Types of Home Health Agencies

Variable	Medicare Home Health Agency	Infusion Nursing Agency	Intrathecal Pump Service Up to two hours*		
Average Visit Duration	One to Two Hours	Up to six hours			
Equipment	Generally not involved	Typically includes infusion equipment	Administration kit (syringes & other disposable items) Pump programmer		
Payor	80% Medicare and TennCare Patients	Private Insurance mainly	Commercial Insurance and Self-Pay Not available		
Age	Approximately 68% Over Age 65+	Majority under Age 65			
Service Provided	44% is skilled nursing. Additional services may include therapy, home health aide, and medical social services.	100% specialized skilled nursing	100% specialized skilled nursing		
Patient Status	Homebound	Patient may or may not be homebound	May or may not be homebound		

*Note: the applicant states each patient may receive 12 visits per year. In addition, the patient should expect to visit his/her physician 4 times per year (page 25, Supplemental 1). Chart Sources include: CN1406-017A, CN1406-018A and CN1411-046 (pending)

 Note to Agency members: The attachment to the Department of Health Report indicated that based on 2013 data, 102,503 service area residents will need home health care in 2018; however 184,157 patients are projected to be served in 2018 resulting in a net excess of (81,654). Please note that this need is calculated for all home health patients, not just those needing home infusion services.

Service Area Demographics

- The proposed service includes all 95 Tennessee Counties.
- Per the TDH project summary, the total population of the 95 county statewide service area is expected to increase by approximately 3.7% from 6,588,698 residents in calendar year (CY) 2014 to 6,833,509 residents in CY 2018.
- The age 64 and younger population accounted for approximately 85.1% of the total population in CY2014. This age group is expected to increase by approximately 12.3% from 5,606,714 in 2014 to 5,731,096 in 2018.

- The 65 and older population accounted for approximately 14.9% of the total population in 2014. This age group is expected to increase by approximately 12.3% between 2014 and 2018.
- The latest 2014 percentage of the statewide population enrolled in the TennCare program is approximately 18.1%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

Service Area Historical Utilization

Using licensure and provider utilization records maintained by the Tennessee Department of Health, the applicant identified approximately 157 existing licensed home health agencies in Tennessee. The name of the agency, location of parent office, licensed counties and utilization for 2011 – 2013 is provided in the table on pages 4-13 of Supplemental 3. As a whole, the agencies served approximately 176,910 patients in 2011 decreasing by 0.5% to 175,924 patients in 2013.

Note to Agency members: The Joint Annual Report does not capture utilization data specific to implanted intrathecal pump therapy patients. There is not a known public database available that reports this type of data.

During review in 2012 of a previous Certificate of Need application for home infusion nursing (Coram Alternative Site Services), HSDA staff contacted the Tennessee Association of Home Care (TAHC) regarding home health providers and the Tennessee Hospital Association (THA) regarding hospital-based home care providers.

TAHC indicated the following:

- TAHC membership applications on file indicate that 224 home health offices (parents and branches) offer infusion therapy services.
- Standard home health policy is that first dose should be completed in the hospital setting.
- The majority of home health agencies partner with an infusion company for administration of the second dose in the home.
- The home health nurse continues to support the patient's needs with observations and reports to the physician. It is unrealistic to think that a home health provider could limit their care to only infusion therapy. Infusion may be the primary need but there are typically patients with multiple chronic illnesses and co-morbidities who need a holistic, multi-disciplinary approach to their health care
- The barriers to home infusion therapy are generally noted as staffing and adequate payment. This is a growing issue for all homecare providers as

- both governmental and commercial payors continue to look to provider payments to cut costs.
- Homebound status is only a Medicare issue. An infusion company would be held to the same standard if it were a Medicare-certified home health agency.

THA's response included that a "typical" home care provider does not provide infusion administration for:

- Patients requiring 6 hour therapies.
- Medicare patients who are not homebound which is a requirement that applies only to Medicare.
- Many non-Medicare patients who are not homebound are served
- Patients requiring first dose administration
- Patients requiring three doses daily

THA also advised that member home health agencies see patients in every county in the state and that there are pediatric programs often affiliated with pediatric hospitals such as Vanderbilt, Methodist LeBonheur, and East Tennessee Children's Hospital.

During review of this application and 2 Coram/CVS Certificate of Need projects for specialty infusion services (please see descriptions for CN1406-017A and CN1406-018A at the end of this summary), HSDA staff received confirmation by phone and by an email from a representative of TAHC that the TAHC information provided in 2012 was still accurate at the time the applicant's proposal was under review in 2014.

Applicant's Projected Utilization

- Per the applicant, implanted pump representatives estimate there were approximately 300 implanted pump patients in Tennessee during 2014.
- The applicant projects serving 120 patients in Year 1 increasing to 240 patients in Year 2
- The applicant is projecting 1,440 total visits in Year 1 increasing to approximately 2,880 visits in Year 2. The applicant bases the projected intrathecal pump patient visit schedule on approximately 12 skilled nursing visits per patient per year.
- IPM's projected patient caseload in Year 1 amounts to approximately 40% of the estimated 300 intrathecal pump patients in Tennessee in CY2014.
- Of the 121 projected implanted pump patients in Year 1, approximately 108 will be treated for diagnoses related to chronic pain, 11 for Cerebral Palsy and 2 for Multiple Sclerosis.

- The applicant estimates that approximately 2.2 million Tennesseans have chronic pain, 21,530 have Cerebral Palsy, and 7,169 have multiple sclerosis.
- A statewide profile by clinical classification by county is shown in the table on pages 28-31 of Supplemental 2.

Project Cost

Major costs of the \$13,038 total estimated project cost shown on page 32 of the application are as follows:

- Office Lease-\$8,738 or 67% of total cost
- Office supplies and pump programmer \$1,300
- Filing fee \$3,000

Applicant's Historical and Projected Data Chart

As noted, Implanted Pump Management LLC is a relatively new organization that has no financial record of operations involving the proposed home health services limited to infusion pump patients.

The projected financial performance of the project appears to be favorable as proceeds from operating revenues cover operational costs. Highlights from the Projected Data Chart on page 35 of the revised application are as follows:

- Projected gross operating revenue increases from \$288,000 on approximately 1,440 total implanted pump patient visits to \$576,000 on 2,880 visits in Year 2.
- The average gross charge is unchanged at \$200 per visit in Year 1 and Year 2
- Salaries include \$125,000 for a full time Director of Nurses and a staff RN in Year 1 increasing to \$180,000 in Year 2, subject to expected increases in patient census.
- Net operating income is favorable at \$134,962 in Year 1 and \$369,562 in Year 2.
- Projected NOI calculates to approximately 46.9% of gross operating revenue in Year 1.
- Deductions from operating revenue for bad debt and charity are \$500 and \$1,000, respectively, in Year 1.

Charges

In Year One of the proposed project, the average charge per visit is as follows:

• The proposed average gross charge is \$200 per intrathecal pump patient visit in the first two years of the project.

- The average deduction for bad debt and charity averages approximately \$1.00 per patient visit.
- As noted, the applicant expects a reimbursement range of \$150-\$250 by most major commercial payors with a home nursing benefit. The applicant states that Medicare does not cover in-home nursing visits for intrathecal pump patients.

Medicare/TennCare Payor Mix

The applicant will not seek Medicare and Medicaid certification for the proposed home health agency limited to implanted infusion pump nursing services.

- Even if the applicant wanted to apply for Medicare/TennCare, it may not be eligible since the proposed limited scope of service would not be providing the full range of home health services prescribed by the Medicare Conditions of Participation.
- As noted, the contracted pharmacies participating in the project will be responsible for billing their fees related to dispensing implanted pump medications.
- The applicant's projected payor mix is 99% commercial insurance and 1% Self-Pay in Year 1.

Financing

The start-up costs for the project will be funded from cash reserves and appear minimal consisting primarily of a security deposit for leased office lease, supplies and the CON filing fee.

Review of IPM's unaudited financial statements and recent checking account statement confirmed the availability of approximately \$132,514 in checking/savings as of June 1, 2014 to fund the \$13,038 proposed project. Per the Balance Sheet, IPM reported total current assets of \$132,514 and total current liabilities of \$102,488 resulting in a current ratio of 1.27 to 1.0.

Note to Agency members: Current Ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant plans to use a 40 to 1 patient to nurse staffing ratio for the proposed agency with each nurse responsible for a geographic area within a 180 mile radius of his/her home of residence. IPM expects to hire approximately 2 full time equivalent (FTE) licensed nurses in Year 1. In addition, the applicant is

prepared to hire a third RN subject to increases in patient census. The home health agency's administrator will also have an assigned patient caseload.

Licensure/Accreditation

If approved, the applicant's proposed home health agency will be licensed by the Tennessee Department of Health.

- The applicant provided information regarding the licensing and accreditation of its existing or pending home health agencies in other sites.
- A copy of IPM's provisional Joint Commission Accreditation award for Home Care effective July 19, 2014 was provided with Supplemental 3.
- The applicant documented that the compounding pharmacies it expects to use to support the project are accredited. A copy of the Pharmacy Compounding Accreditation Board (PCAB) manual was provided with Supplemental 3 to document the standards related to this type of accreditation.
- As noted, the applicant also provided responses to questions and concerns addressed by TDH staff during its 60-day review period. These are shown in the TDH summary with attachments.

Corporate documentation, copies of the office lease, copies of related clinical literature, copies of the major ICD-9 and CPT codes that apply to implanted intrathecal pump patients, copies of policies and procedures, including Quality Assurance and Nurse Training Manual, and a copy of Humana Health Insurance provider manual are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **two** years.

Note to Agency members: Should the Agency choose to approve this application, Staff recommends the Agency limit any future expansion of services by requiring a new application to expand services beyond implanted intrathecal pump infusion services rather than a modification request through the General Counsel's Report. This could be accomplished with the following condition:

Home Health Agency services are limited to specialized skilled nursing services under physician ordered plans of care for patients with surgically implanted intrathecal pumps. The expansion of services beyond the home implanted pump infusion services described in the application will require the filing of a new certificate of need application.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

<u>CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:</u>

There are no other Letters of Intent for other health care organizations in the service area proposing this type of service.

Pending Applications

Pentec Health, Inc., CN1411-046, has a pending application that will be heard under simultaneous review with CN1407-027 at the HSDA meeting on March 25, 2015 for the establishment of a home health agency to provide intrathecal pump services to patients across 92 counties of Tennessee. The estimated project cost is \$142,028.00.

The Home Option by Harden Healthcare, CN1501-001, has a pending application that will be heard under CONSENT CALENDAR REVIEW at the March 25, 2015 Agency meeting for the initiation of home health services in Blount, Campbell, Claiborne, Grainger, Monroe, Morgan, Roane and Scott Counties focusing on home health services to eligible individuals covered under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), United States Department of Labor. If approved, the applicant's sister agency, Gentiva Certified Healthcare Corporation, will de-license the same 8 counties. The Home Health Option by Harden is located at 800 Oak Ridge Turnpike, Suite A208, Oak Ridge (Anderson County), TN 37830 and is currently licensed in Anderson, Jefferson, Knox, Loudon, Sevier and Union Counties. The estimated project cost is \$38,000.00.

Denied Applications:

Home Care Agency of Middle Tennessee, CN1001-001D, was denied at the June 23, 2010 Agency meeting for the establishment of a home care organization focusing on a full range of home health services and skilled nursing psychiatric services for the elderly population in a four (4) county service area including Davidson, Rutherford, Sumner, and Williamson Counties from a parent office located at 5115 Maryland Way, Brentwood, (Williamson County), Tennessee. The estimated project cost was \$69,000.00. Reasons for Denial: There is not a need as there are other agencies in the proposed service area that are providing home health

services, including services to the mentally ill, and it is not economically feasible to have another agency. The project will not contribute to the orderly development of adequate and effective health care.

Rainbow Home Health, CN1111-045D, was denied at the February 22, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services, including skilled nursing, physical/occupational/speech therapies, and medical social services for individuals residing in Cheatham County from a home office located at 112 Frey Street in Ashland City (Cheatham County), Tennessee 37015. The estimated cost was \$262,600.00. Reasons for Denial: the prevailing reason for the vote leading to the denial of the project (4 ayes, 6 nays, 0 ties) was based on concerns with nature and scope of information provided by the applicant that did not support the need for the project, the economic feasibility or the orderly development of the project.

Rainbow Home Health, CN1203-013D, was denied at the June 27, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services from a home office located at 112 Frey Street, Ashland City (Cheatham County), Tennessee. The estimated project cost was \$27,950.00. Reasons for Denial: the application was denied by unanimous vote based on the following: there was no need due to services being adequately provided by existing licensed agencies in the service area; the project was not economically feasible due to the numbers not being justified or showing how the applicant could feasibly provide the service; and the project did not contribute to orderly development as it will impact the utilization and staffing of existing agencies in the service area.

Critical Nurse Staffing, CN1210-049D, was denied at the January 23, 2013 Agency meeting for the establishment of a home care organization located at 575 Oak Ridge Turnpike, Oak Ridge (Anderson County), Tennessee focusing on individuals eligible for benefits under either the Energy Employees Occupational Illness Compensation Program Act or the Federal Black Lung program that reside in Anderson, Campbell, Knox, Loudon, Monroe, Morgan, Roane, and Union Counties. The estimated project cost was \$155,937.00. Reasons for Denial: There was no real need - care was being adequately provided by other agencies in the proposed service area and adequate evidence did not support or prove that there was a need for the proposed agency.

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby, Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was \$177,800.00. Reasons for Denial: The need for the

proposed agency was not supported in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility - the project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.

Outstanding Certificates of Need:

Coram Alternate Site Services, Inc. d/b/a Coram Specialty Infusion Services CN1406-018A has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to the provision and administration of home infusion products and related ancillary services ancillary to its pharmacy services in a 25 county service area of West Tennessee, including the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, McNairy, Madison, Obion, Perry, Shelby, Stewart, Tipton, Wayne and Weakley Counties. The parent office will be located in its licensed home infusion pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee, 38134. The estimated project cost is \$98,000.00. Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the Tennessee Department of Health. The initial licensing inspection for the parent office in Memphis, TN has been scheduled for March 13, 2015. An Annual Project Report is due on or before July 1, 2015.

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, CN1406-017A, has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, and Washington Counties, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is \$95,200.00. Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the

Tennessee Department of Health. Notice of the inspection date is pending. An Annual Project Report is due on or before July 1, 2015.

Maxim Healthcare Services, CN1406-015A, has an outstanding Certificate of Need that will expire on October 1, 2016. The project was approved at the August 27, 2014 Agency meeting for the initiation of home health care services in a 5 county service area including Carter, Johnson, Sullivan, Unicoi, and Washington Counties focusing primarily on private duty hourly care to TennCare medically complex pediatric patients. Maxim Healthcare Services seeks an unrestricted home health agency license and will obtain Medicare certification to meet TennCare provider enrollment requirements. The estimated project cost is \$463,825.00. Project Status Update: per 2/27/15 e-mail from legal counsel for Maxim Health Care Services, the project was appealed but it appears that the parties have reached a settlement and the appeal may be dismissed in the near future. Confirmation of same will follow as soon as possible.

Hemophilia Preferred Care of Memphis, CN1202-002, has an outstanding certificate of need that will expire on August 1, 2015. The CON was approved at the June 27, 2012 agency meeting for the establishment of a home health agency and the initiation of home health services limited to patients suffering from hemophilia or similar blood disorders who are patients of the pharmacy operated by Hemophilia Preferred Care of Memphis. The estimated project cost is \$43,000. Project Status: The applicant requested and received approval at the June 25, 2014 Agency meeting for a one year extension from August 1, 2014 to August 1, 2015.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG 03/10/2015



STATE OF TENNESSEE DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH COMMISSIONER

BILL HASLAM GOVERNOR

November 24, 2014

Ms. Melanie Hill, Executive Director Health Services and Development Agency Andrew Jackson Building Deaderick Street Nashville, TN 37243

HAND-DELIVERED

Re: Certificate of Need Application No. <u>CN1407-027 filed by Implanted Pump Management LLC</u>

Dear Director Hill:

The Tennessee Department of Health (TDH) has been reviewing the above-referenced application for a Certificate of Need (CON) that is set to be heard on December 17, 2014. TDH has devoted a great deal of time to its review but finds that issues that have arisen regarding TDH's regulatory responsibilities require more effort, and thus more time, before its report to the Health Services and Development Agency can be finalized. In order to provide sufficient time for TDH to complete its work, TDH requests that the HSDA defer hearing this CON application for 90 days, as is permitted by statute.

THD also requests that any other CON applications for similar services received by HSDA also be so deferred.

Sincerely,

John J. Dreyzehner, MD, MPH, PACOEM

Commissioner

JJD/JO/tls

5th Floor, Andrew Johnson Tower 710 James Robertson Parkway * Nashville, TN 37243 (615) 741-3111 * www.tn.gov/health

LETTER OF INTENT



LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Tennesseean	which is a newspaper
of general circulation in [see attachment] (Name of Newspaper) , Tennessee, on or before July	y 2nd , 2(14
for one day.	(Month / day) (Year)
~	
This is to provide official notice to the Health Services and Development Agency an accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services a	nd all interested parties, i and Development Agency
Implanted Pump Management LLC	
(Name of Applicant) (Facility Type-E)	xisting)
owned by: Roy Putrino with an ownership type of Sing	gle Member LLC
and to be managed by: Roy Putrino intends to file an application for	or a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:	
The establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The estimated project cost is \$8.100	O. The agency will utilize one office located at
The establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The estimated project cost is \$8,100 200 Prosperity Place #102. Knowlile, TN 37923, to service the entire state. Services will be provided within all 95 Tennessee counties listed as follows: Anderson Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Cieiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, Dekalb, Dickson, Dyer, Fayett Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Je Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, F Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, W.	i, Bedford, Benton, Biedsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Beny, Birkatt, Bolf, Button, Diseas, Bonno
ZOU Prosperity Prace #102, Knowlie, 1 N 37923, to service the entire state. Services will be provided within all 95 Tennessee counties listed as follows: Anderson Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Cielborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, Dekalb, Dickson, Dyer, Fayett Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Je Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, F Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, W	i, Bedford, Benton, Biedsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Beny, Birkatt, Bolf, Button, Diseas, Bonno
The anticipated date of filling the application is: July 7th The anticipated date of filling the application is: July 7th July 7th July 7th	i, Bedford, Benton, Biedsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Beny, Birkatt, Bolf, Button, Diseas, Bonno
The anticipated date of filling the application is: Sully 7th Part Part	, Bedford, Benton, Bledsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane, Vayne, Weakley, White, Williamson, Wilson.
The anticipated date of filling the application is: July 7th The contact person for this project is Melissa Hess (Contact Name) Who may be reached at: Implanted Pump Management (Contact Name)	, Bedford, Benton, Bledsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Pery, Pickett, Polk, Pulnam, Rhea, Roane, Vayne, Weakley, White, Williamson, Wilson. Director of Nursing (Title)
The anticipated date of filling the application is: Service the application State Service State Service State Service State Service State Service State Service State S	, Bedford, Benton, Bledsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane, Wayne, Weakley, White, Williamson, Wilson. Director of Nursing (Title) Jace #102
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The anticipated date of filling the application is: Service the application July 7th July 7th	, Bedford, Benton, Bledsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane, Wayne, Weakley, White, Williamson, Wilson. Director of Nursing (Title) Jace #102
The anticipated date of filling the application is: Sully 7th	, Bedford, Benton, Bledsoe, Blount, Bradley, te, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Pery, Pickett, Polk, Pulnam, Rhea, Roane, Vayne, Weakley, White, Williamson, Wilson. Director of Nursing (Title) Jace #102 01) 475-9635

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville. Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

-Application
Implanted Pump
management
CN1407-027

		ingel Special est
Name of Facility, Agency, or Institution	<u>on</u>	JIII. 28
Implanted Pump Management LLC		•
Name		
200 Prosperity Place #102		Knox
Street or Route		County
	TARSES.	37923
City	State	Zip Code
Contact Person Available for Respon	ses to Questio	o <u>ns</u>
Melissa Hess		Director of Nursing
Name		Title
Implanted Pump Management		info@IPMservices.org
		Email address
200 Prosperity Place #102	Knoxville	TN 37923
1/25/34/59/2		State Zip Code
Owner of the Facility, Agency or Instit	ution	
Pay Putring		1 1004 475 0005
		201-475-9635 Phone Number
		Passaic
Street or Route		County
Wayne	NJ	07470
City	State	Zip Code
Type of Ownership of Control (Check	One)	11
A. Sole Proprietorship B. Partnership C. Limited Partnership	- G Poli	vernment (State of TN or itical Subdivision)
	Implanted Pump Management LLC Name 200 Prosperity Place #102 Street or Route Knoxville City Contact Person Available for Response Melissa Hess Name Implanted Pump Management Company Name 200 Prosperity Place #102 Street or Route Employee Association with Owner Owner of the Facility, Agency or Institute Roy Putrino Name 1401 Valley Road Street or Route Wayne City Type of Ownership of Control (Check A. Sole Proprietorship B. Partnership	Name 200 Prosperity Place #102 Street or Route Knoxville City State Contact Person Available for Responses to Question Melissa Hess Name Implanted Pump Management Company Name 200 Prosperity Place #102 Street or Route Employee Association with Owner Roy Putrino Name 1401 Valley Road Street or Route Wayne City Type of Ownership of Control (Check One) A. Sole Proprietorship B. Partnership B. Partnership C. Limited Partnership G. C. Limited Partnership G. C. Limited Partnership State

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5.	5. Name of Management/Operating Entity (If Applicable)					
	Name					
	Stre	eet or Route			County	
	City				ate Zip Code	
	City			O.	ate zip odde	
		FERENCE THE APPLICABLE IT			THE APPLICATION IN ORDER ON ALL ATTACHMENTS.	R AND
6.	Leg	al Interest in the Site of the Ins	titution (Chec	k One)	
	A.	Ownership	\Box	D.	Option to Lease	
	B. C.	Option to Purchase Lease of Years		E.	Other (Specify) Rent	
	0.	Lease of Tears	1			
		FERENCE THE APPLICABLE IT			THE APPLICATION IN ORDER ON ALL ATTACHMENTS.	RAND
7.	Typ	e of Institution (Check as appr	opriate	more	than one response may apply)	
	A. B.	Hospital (Specify) Ambulatory Surgical Treatment		l. J.	Nursing Home Outpatient Diagnostic Center	
	C.	Center (ASTC), Multi-Specialty ASTC, Single Specialty	\pm	K. L.	Recuperation Center Rehabilitation Facility	Ħ
	D.	Home Health Agency		M.	Residential Hospice	口
	E. F.	Hospice Mental Health Hospital	\blacksquare	N.	Non-Residential Methadone Facility	
	G.	Mental Health Residential		0.	Birthing Center	三
	Н.	Treatment Facility Mental Retardation Institutional		P.	Other Outpatient Facility (Specify)	
		Habilitation Facility (ICF/MR)		Q.	Other (Specify)	
8.	Pur	pose of Review (Check) as appl	ropriate-	more	e than one response may apply)	
	A.	New Institution		G.	Change in Bed Complement [Please note the type of change	}
	B. C.	Replacement/Existing Facility Modification/Existing Facility	荁		by underlining the appropriate	
	D.	Initiation of Health Care			response: Increase, Decrease, Designation, Distribution,	*
		Service as defined in TCA § 68-11-1607(4)			Conversion, Relocation]	
	_	(Specify)		Ha	Change of Location	
	E. F.	Discontinuance of OB Services Acquisition of Equipment		Ŀ	Other (Specify)	
		danaman a. mdanbunam				

9.	Bed Complement Data Not Applicable Please indicate current and proposed distribution and certification of facility beds.						
	A.B.C.D.E.F.G.H.I.J.K.L.M.N.O. P.Q.R. S.T.U.	Medical Surgical Long-Term Care Hospital Obstetrical ICU/CCU Neonatal Pediatric Adult Psychiatric Geriatric Psychiatric Child/Adolescent Psychiatri Rehabilitation Nursing Facility (non-Medicai Nursing Facility Level 1 (Med Nursing Facility Level 2 (Med Nursing Facility Level 2 (Med Nursing Facility Level 2 (dually certified Medicaid/Medical ICF/MR Adult Chemical Dependency Child and Adolescent Chem Dependency Swing Beds Mental Health Residential T Residential Hospice TOTAL *CON-Beds approved but not ye	c d Certified) dicaid only) dicare only) are) v ical	Current Beds Licensed *CON	Staffed Beds	Beds Proposed Grant Gra	TOTAL Beds at Completion
10. 11.		ledicare Provider Number Certification Type ledicaid Provider Number	Not Applicable Not Applicable				
		Certification Type	INOT Applicable				
12.	lf	this is a new facility, will co	ertification b	e sought for Med	licare and/	or Medicaio	1? No
13.	Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? No If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.						the please
	D	iscuss any out-of-network	relationships	s in place with Mo	COs/BHOs	in the area	١.

NOTE:

Section B is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. **Section C** addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. **Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.**

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.
- II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.
 - A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

IMPLANTED PUMP MANAGEMENT, LLC.

Specializing in The Management of Pain and Spasticity
Implanted Pump Therapies

SECTION B: PROJECT DESCRIPTION

I. Please provide a brief summary of the project not to exceed two pages. Topics to be discussed in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Implanted Pump Management (IPM) proposes to introduce an intrathecal home infusion program that services Tennessee patients with implanted pumps. The proposed services would be provided to patients in their home and in third party facilities. IPM specializes in only one type of home infusion therapy – intrathecal home infusion management. This specific type of home infusion is a very intricate, high-tech therapy that requires extensive knowledge, understanding, equipment, and resources to provide effectively and safely to the patient population in need. The service includes refills, titrations, 24-hour on call services, and an advanced information technology program that simulates telemedicine for participating providers. Only individuals with an implanted programmable intrathecal pump will be able to benefit from the proposed service.

Implanted Pump Management (IPM) is a New Jersey LLC formed in 2012, registered to do business in Tennessee since October of 2013. The proposed service area requested is broad, based solely on the nature of the proposed therapy. Two registered nurses with a sole focus in intrathecal pump management will be utilized to implement physician orders in terms of managing the intrathecal pump. Based on our specialization with a niche population, consisting of many patients whom are homebound, our nurses will potentially be responsible for a vast service area that encompasses the entire state of Tennessee. We intend to utilize one full-time RN per 40 patients. The registered nurses will physically travel to each individual's home to implement the intrathecal management. The proposed structure differs vastly from conventional Home Health structures in that the IPM RN will have a larger coverage area but, most likely, a smaller patient caseload than that of a traditional home care nurse in Tennessee. For example, the IPM RN may travel two hours to see their intrathecal patient, then travel two hours back in one day. A traditional home care nurse will often times travel two hours total but, due to a condensed geographical area, see four patients in that one day.

According to data provided by Medtronic, a leading pump manufacturer, 300 residing individuals currently have intrathecal pumps in the state of Tennessee. Based on this data as well as physician requests for IPM to enter the state of Tennessee, IPM has decided to introduce this proposal. Although the state of Tennessee currently has other companies that offer a wide range of infusion therapy services, these companies oftentimes offer minimal services of intrathecal home management, and none focus solely on intrathecal pump management. IPM feels that our sole focus on intrathecal pump management allows us to offer patients higher outcomes in regards to safety, efficacy, therapy success, and overall a higher quality of life.

The estimated project cost will not include any construction, modification and/or re-configuration of existing properties. IPM will designate one RN as an agency director that will utilize a rented office to serve as the location required for administrative purposes. The only activities performed in the IPM office will be clerically-based, i.e. record keeping, housing of policies, and acting as a designated physical address for a main computer utilized for electronic patient charting. The actual care provided will always be performed in each individual patient's home or in third party facilities.

IMPLANTED PUMP MANAGEMENT, LLC.

Specializing in The Management of Pain and Spasticity Implanted Pump Therapies

The estimated staffing required for the state of Tennessee will be two full-time employees (FTEs) during the first year of operation and three during the second. The full-time employees will be registered nurses that hold valid Tennessee Board of Nursing Licenses and are rigorously trained in all aspects of intrathecal pump management. The financial requirements for IPM to maintain the proposed services will include salaries and minor office supplies. The estimated cost of the first year of operation is \$134,962. Due to the structure proposed by IPM for staffing and implementation strategy, the low cost expenditure per year will offset the higher costs of healthcare as a whole, based on the fact that the clinical staff is mobile and all corporate costs and functions will remain at a separate location.

The type of services provided by the proposed HHA would be skilled nursing services and infusion services. IPM plans to adhere to and practice all TN statutes dictated for the proper administration of a Home Health Agency. Each individual will be admitted based on need, financial viability, and clinical appropriateness. IPM will perform a full nursing assessment upon every patient contact, full intrathecal pump evaluation, and implement any MD orders involving the intrathecal pump management. Not only will IPM implement MD orders in regards to the intrathecal pump, but IPM will also utilize the existing HHAs in the state to refer individuals for additional services not in IPM's scope of practice. IPM intends to establish working relationships with the local HHAs to determine their individual scope of practice to determine the best pathway for each individual. IPM will refer the individual to the appropriate licensed HHA that best fits that individual's medical needs.

The MD responsibilities will not change for the individual patient with the introduction of the proposed service. The addition to IPM will only relieve some of the burden of the intrathecal pump management for the MD. The MD will still be responsible for seeing the patient in his/her office as needed. The MD will still be required to actively participate in the writing of orders and be available for IPM if concerns or abnormal findings are present. The proposed service will:

- 1. Decrease MD workload and staff requirements for office staff
- 2. Eliminate the procurement of intrathecal medications for refills
- 3. Eliminate liability for inaccurate pump refills or programming
- 4. Eliminate tracking of alarm dates for patients by the MD
- 5. Reduce overall workload of MD office in regards to the intrathecal pump patients The HHA or IPM will be responsible for:

- 1. Full nursing assessments and the required reporting of any abnormal findings
- 2. Monitoring and tracking all alarm dates
- 3. Coordination of services for patients
- 4. Contracting with Infusion pharmacies for intrathecal medications
- 5. All aspects of billing
- 6. Maintaining all required polices and procedure for HHA licensure in the state of TN
- 7. Education and training for patients and staff
- 8. Maintaining all administrative functions for the HHA licensure

The proposed model from IPM will increase physician expertise and awareness of the patient by offering the MD an insight of the individual's home environment, dynamics, and available support systems. This model closely mimics many principles of tele-medicine. Instead of the MD only seeing the patient for refills and focusing on that task, the MD will not get documentation complete with pictures of the whole patient.

IMPLANTED PUMP MANAGEMENT, LLC.

Specializing in The Management of Pain and Spasticity
Implanted Pump Therapies

- II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.
- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A. -E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B. -E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

The development of the proposed services will be able to be initiated within thirty days once postlicensure and certificate of need requirements have been met.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Not Applicable (NA)

C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

8. Home Health Services

The need to provide home health services in the state of Tennessee in regards to intrathecal home infusion management is great. Based on the variety of diagnoses that the proposed individuals to be serviced have—ranging from Multiple Sclerosis, cerebral palsy, traumatic brain injuries, and reflex sympathetic dystrophy to chronic pain—they are oftentimes homebound due to debilitation and benefit greatly from homecare. In the traditional model, the intrathecal management occurs in the medical doctor's office. For many individuals, this scenario presents many challenges in regards to travel, expenses, ability to drive, and oftentimes absence of caregiver support. The home management model allows for more effective care to be delivered in a timelier manner. Any physician orders can be implemented in 48 business hours. In the traditional MD office, implementation of orders may take up to two weeks based on appointment availability. The specific type of home management model we propose is absent in most of Tennessee while there are numerous individuals that could benefit from a proactive, quality intrathecal home management company.

D. Describe the need to change location or replace an existing facility.

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Not Applicable (NA)

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

Not Applicable (NA)

- III. (A) Attach a copy of the plot plan of the site on an 8 $\frac{1}{2}$ " x 11" sheet of white paper which <u>must</u> include:
- 1. Size of site (in acres);
- 2. Location of structure on the site; and
- 3. Location of the proposed construction.
- 4. Names of streets, roads or highway that cross or border the site.

 Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

The proposed model will allow for all patient skilled care to be provided in each individual patients home. Only a small office space will be utilized for the physical location necessary to contain required personnel, and patient records. Please see Plot Plan (Attachment B.3.a.).

(B) Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

The executive suite building in which our office is located is easily accessible to the public and is close to Routes 40 and 75. It is in proximity to other businesses. These facts are not, however, applicable to our services rendered.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (nothing private or semi-private), ancillary areas, equipment areas, etc. on an 8 $\frac{1}{2}$ " by 11" sheet of white paper.

Please refer to the attached Floor Plans (Attachment B.5.).

- V. For a Home Health Agency or Hospice, identify:
- 1. Existing service area by County;

Not Applicable (NA)

2. Proposed service area by County;

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IPM intends to provide intrathecal home infusion services to all 95 counties within the state of Tennessee, listed as follows: Anderson, Bedford, Benton, Bledsoe, Blount, Bradley, Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, DeKalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putnam, Rhea, Roane, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, Wayne, Weakley, White, Williamson, Wilson.

3. A parent or primary service provider;

Our office location at 200 Prosperity Place in Knoxville, TN is 8' by 10' (80 square feet total). This space is comparable in cost to other similar office rentals in Knoxville. This space is large enough to accommodate one nurse and all necessary office supplies, i.e. desk, computer, telephone, locked filing cabinet, nursing supplies, etc. The office will never be occupied by more than one RN simultaneously. Regarding 24-hour emergency and on call services, these will be provided by a single RN DON/Administrator with over 9 years of experience in intrathecal therapy. (IPM may choose to contract for call center services in order to provide emergency and on call care at a future date when it is within our budget.) Contracted pharmacy services will be provided by staff at a remote location at 1401 Valley Road in Wayne, NJ 07470.

4. Existing branches; and

Due to the nature of intrathecal infusion therapy whereby our RNs visit patients intermittently on average over a long period of time to perform refills, we are able to offer comprehensive coverage of our services across the entire state of Tennessee by employing two full-time employees to provide skilled nursing services during our first year of operation. We project that the number of FTEs will increase to three by year two. Our administrator, who will also be employed as one of the full-time RNs, will utilize our home office. It will not be necessary for our other employed nurses to utilize branch offices, nor will we have a need to utilize a branch office for any other function—pharmacy and call center—as contracted professionals will provide these at remote locations.

5. Proposed branches.

The proposed service area is to include all counties of Tennessee. Due to the specific and detailed nature of the proposed home care management service, IPM will be able to sufficiently and safely provide quality intrathecal home care throughout the entire state of Tennessee without having to utilize branch offices.

Absolutely no patients, caregivers, or physicians will ever be visiting the home office for conferences or meetings as all necessary communication will take place either over the phone (directly with IPM nursing staff or via contracted pharmacy call center) or within the comfort of a patient's home or other location as designated convenient for the patient. Regarding on-call and emergency services, these will be rendered in the same fashion—the home office will be utilized solely for administrative purposes.

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART Not Applicable

lal	Total															から 明後 子を一大かる		Not Applicable
Proposed Fina Cost/ SF	New		- Children School Street							Constitution of the last of th						Residence of the second		Not Applicable
	Renovated									-								Not Applicable
_ o	Total																	Not Applicable
Proposed Final Square Footage	New																	Not Applicable
Prop Squa	Renovated														7			Not Applicable
Proposed Final	Location										Į.							Not Applicable
Temporary	Location	2																Not Applicable
Existing	SF																	Not Applicable
Existing	Location															Time in a south		Not Applicable
A. Unit / Department														B. Unit/Depart. GSF Sub-Total	C. Mechanical/	Electrical GSF	D. Circulation /Structure GSF	E. Total GSF

- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):
 - 1. Adult Psychiatric Services
 - 2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
 - 3. Birthing Center
 - 4. Burn Units
 - 5. Cardiac Catheterization Services
 - 6. Child and Adolescent Psychiatric Services
 - 7. Extracorporeal Lithotripsy
 - 8. Home Health Services
 - 9. Hospice Services
 - 10. Residential Hospice
 - 11. ICF/MR Services
 - 12. Long-term Care Services
 - 13. Magnetic Resonance Imaging (MRI)
 - 14. Mental Health Residential Treatment
 - 15. Neonatal Intensive Care Unit
 - 16. Non-Residential Methadone Treatment Centers
 - 17. Open Heart Surgery
 - 18. Positron Emission Tomography
 - 19. Radiation Therapy/Linear Accelerator
 - 20. Rehabilitation Services
 - 21. Swing Beds
- D. Describe the need to change location or replace an existing facility.
- E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:
 - 1. For fixed-site major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 - 1. Total cost ;(As defined by Agency Rule).
 - 2. Expected useful life;
 - 3. List of clinical applications to be provided; and
 - 4. Documentation of FDA approval.
 - b. Provide current and proposed schedules of operations.
 - 2. For mobile major medical equipment:
 - a. List all sites that will be served;
 - b. Provide current and/or proposed schedule of operations;
 - c. Provide the lease or contract cost.
 - d. Provide the fair market value of the equipment; and
 - e. List the owner for the equipment.
 - 3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In

the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

- III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which <u>must</u> include:
 - 1. Size of site (in acres);
 - 2. Location of structure on the site; and
 - 3. Location of the proposed construction.
 - 4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for <u>all</u> projects.

- (B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.
- IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: <u>DO NOT SUBMIT BLUEPRINTS</u>. Simple line drawings should be submitted and need not be drawn to scale.

- **V.** For a Home Health Agency or Hospice, identify:
 - 1. Existing service area by County;
 - 2. Proposed service area by County;
 - A parent or primary service provider;
 - 4. Existing branches; and
 - 5. Proposed branches.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

36 QUESTIONS

NEED

- 1. Describe the relationship of this proposal toward the implementation of the State Health Plan and <u>Tennessee's Health</u>: <u>Guidelines for Growth</u>.
 - a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.
 - b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)
- 2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.
- 3. Identify the proposed service area <u>and</u> justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).
- 4. A. Describe the demographics of the population to be served by this proposal.
 - B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.
- 5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.
- 6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

ECONOMIC FEASIBILITY

- 1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)

- The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
- The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
- For projects that include new construction, modification, and/or renovation;
 <u>documentation must be</u> provided from a contractor and/or architect that support the estimated construction costs.

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SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

The proposed service model will protect, promote and improve the health of Tennesseans over time by creating a proactive option for intrathecal home care management. The models overall goal is better outcomes, access to care and quality clinical management of the intrathecal pump. This goal can only assist in improving the quality of life of the Tennesseans whom can utilize this service.

- a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.
- 1. The need for home health agencies/services shall be determined on a county by county basis.

Due to the highly specific nature of this therapy, Tennessee residents that will benefit from, and for whom our services will indeed be necessary in achieving optimal treatment outcomes associated with their individual condition, will likely be dispersed throughout the entire state of Tennessee with no regard for geographic predictability. We can anticipate servicing such a broad area because of the fact that intrathecal pump patients often drive great distances (3 or 4 hours is commonplace) to a physician office in order to receive pump refills and maintenance. Thus, patients living in extremely rural areas of the state will present a need for our services as crucial as those living in more populated areas, even though this need may not be as visible and apparent.

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed area.

These percentages are not reliably indicative of the need for our services in Tennessee. We humbly ask that you consider this specialization and the associated clinical need for our services when reviewing this section's applicability as indicative of the need for our services within your state.

Using recognized population sources, projections for four years into the future will be used.

These sources are unavailable and not applicable to our services and patient population.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, an estimation will be made as to how many patients could be served in the future.

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Due to our specialization of services and the niche population of patients we will be seeing, this standard is not applicable to our company. Unlike traditional infusion services, the typical indicators cannot be used such as number of additional days in the hospital due to delays in initiation home infusion services, or number of days of delay in initiation of home infusion services. This particular therapy is only initiated by a neurosurgeon, or implanting physician, not by a Registered Nurse. The RN can continue and assist with the home management, but the proposed service model will assist only with management.

Two important indicators for this specific type of therapy might be:

- Average number of days pts must wait for MD appointments for required dose changes
 (7 to 10 business days)
- Average number of days pts must wait for required dose changes with IPM intrathecal home management (1 business day)
- Average number of hospitalizations for pump complications per year utilizing the MD office model (2/year)
- Average number of hospitalizations for pump complications per year utilizing IPM proposed model (0.2/year)

5. Documentation from referral sources:

- a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.
- b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.
- c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.
- d. The applicant shall provide information concerning whether a proposed agency would provide services different from those offered by existing agencies.

IPM has obtained three letters of referral from pump manufacturers elucidating the immediate need for our services within the state of Tennessee (see Attachment C.Need-1.a.5.Manufacturers.). In addition, we have obtained letters from two implanted pump patients in Tennessee indicating immediate need of our services (see Attachment C.Need-1.a.5.Patients.). Points indicating this need cited by the manufacturers include the documented and steady increase in pump utilization throughout the Southeast, the need for the provision of this therapy in the home as patients with the associated diagnoses result in ambulatory issues, and the sole focus of our company in intrathecal home infusion therapy as being integral to obtain optimal outcomes and quality of life for this population.

Medtronic is the worlds largest medical technology company, offering a depth of innovative therapies to fulfill their mission of alleviating pain, restoring health, and extending life. Medtronic was founded in 1949, with their world headquarters in Minneapolis, Minnesota. Medtronic has several different divisions, including Neuromodulation, Spine and Surgical Therapies. Medtronic serves 140 countries and is MDT on the NYSE (New York Stock Exchange). The Smokey Mountain Medtronic district has provided IPM with documentation that the proposed services would be beneficial for the individuals in Tennessee whom utilize the Medtronic Implantable Intrathecal Pump. The proposed service model would actually

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Therapies. Medtronic serves 140 countries and is MDT on the NYSE (New York Stock Exchange). The Smokey Mountain Medtronic district has provided IPM with documentation that the proposed services would be beneficial for the individuals in Tennessee whom utilize the Medtronic Implantable Intrathecal Pump. The proposed service model would actually facilitate an increase in pump sales for Medtronic due to the elimination of the MD burden of care for the intrathecal pump. IPM is not affiliated with Medtronic formally, but Medtronic recommend the proposed services.

Flowonix is another manufacturer of a programmable implanted intrathecal pump. Flowonix home headquarters is located in New Jersey, but they do have a national presence with intensity in the state of Tennessee. Flowonix is a medical device company dedicated to helping those who suffer from chronic disorders. Our team has decades of experience developing unique and reliable medical devices to improve patients' quality of life. Using one of a kind technology that delivers industry-leading accuracy, Flowonix has developed an implantable drug pump designed to deliver therapeutic drugs into the spine to relieve a variety of chronic disorders and help patients return to normal lives. Flowonix is focused on alleviating chronic pain. We are dedicated to working with healthcare professionals to help ease suffering and allow people to reclaim their lives through innovation and therapy advancements.

The data required to breakdown the patient need based on county of residence is not available. This information is proprietary to Medtronic and not available to the public. Medtronic provided the number of pts in Tennessee, but no further information will be provided based upon the percentage of pts in each county. As Flowonix is a relatively new player in the implantable intrathecal market, and their pump numbers are continuously increasing within the state of Tennessee, they could not provide an accurate projection to IPM.

- 6. The proposed charges shall be responsible in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.
 - b. The average cost per patient upon the projected number of visits per patient shall be listed.

In light of the fact that there are currently, to our knowledge, no other companies in Tennessee that provide all aspects of intrathecal home infusion therapy that can serve as comparisons, this standard is not applicable.

Referring physicians would refer their patients for IPM to do all pump refills, titrations, MRI checks and changes in status in the homecare setting.

b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c).

Not Applicable (NA)

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

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Not Applicable (NA)

3. Identify the proposed service area <u>and</u> justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on a 8 ½" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e. no highlighters, pencils, etc.).

Based upon indications given us by the leading pump manufacturer Medtronic, IPM will service all counties and demographic areas within the state of Tennessee (see Attachment C. Need-3.). Our potential service area is broad and is the result of our niche population being geographically dispersed; this is due to the fact that the diagnoses which will warrant our services—those causing severe spasticity and pain—are unrelated to population demographics of any type.

4. a. Describe the demographics of the population to be served by this proposal.

The need for the proposed home intrathecal pump management will directly affect individuals that have an implanted intrathecal pump for one of two main diagnoses: pain and/or intractable spasticity. The two indications for the intrathecal pump create a varied patent population that could benefit from pump home management.

The individual with chronic pain can range from highly debilitated to possibly having the ability to work full-time. The individual with intractable spasticity most generally suffers from diseases such as:

Multiple sclerosis Cerebral palsy Traumatic brain injury Spinal cord injuries Varied neurological disorders

The patient population that suffers from intractable spasticity is a very individualized, highly specific patient group with special needs and particular service requirements. Due to the nature of the disease processes involved, many of the patients suffer from some form of movement disorder and or chronic pain. Both of these diagnoses present a challenge both physically and economically when the patients are forced to have their intrathecal pump management performed in the MD office. Although the MD office model is effective for some, the majority of the intended population benefits from home infusion of their intrathecal pump.

The proposed home management model will allow registered nurses to manage all aspects of the implanted intrathecal pump in the comfort of the patient's home. The registered nurse will obtain signed MD orders for all implementation of the implanted pump therapy. IPM will act as an extension to the MD's office to assist in facilitating the highest possible therapy outcomes. IPM will fill, titrate, trouble shoot and supply medication and manage the intrathecal pump in the home care setting. The traditional location for pump refill, titrations, and troubleshooting is the doctor's office. Due to the inability to ambulate, economic restraints, and caregiver availability, many of the patients suffer hardships to physically get to the doctors office for a pump therapy that can be safely managed at home.

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b. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

While the immobility of the intended population is expected to present as the most pressing of special needs, IPM will aggressively attempt to provide our highly specialized services to any resident in need of pump management, regardless of age, race, ethnicity, gender, or income. As IPM intends to offer services based upon the principle of non-discrimination, our referrals will be based on the need for intrathecal infusion therapy management and the likelihood of positive treatment outcomes rather than characteristics pertaining to the patient population, which are otherwise unrelated.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

To our knowledge there is no single provider that supplies intrathecal home management as proposed in IPM's model. Any providers that provide home intrathecal management do not specialize as IPM does. IPM feels that the specialized, sole focus on intrathecal therapy management sets us apart from the rest. Historically, intrathecal therapy has been riddled with errors and negative results. By adopting the management model of IPM, the therapy has higher success rates due to quality, education, knowledge and overall proactive approach.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

The need for intrathecal home management in Tennessee has been derived from medical doctors practicing in Tennessee inquiring about services available. The projected patient population is derived from the number of implanted pump patients in the state of Tennessee. Per Medtronic statistics, 300 intrathecal pumps are currently in use in the state of Tennessee. As this number is supplied directly from the pump manufacturer, it is an adequate identifier of additional resources needed in the state of Tennessee.

The estimated number of individuals with implanted intrathecal pumps in the state of Tennessee is 300. IPM proposes utilization of services to 40% of this intended population—approximately 120 individuals. This estimation is conservative in approach, but IPM feels the targeted percentage is attainable and realistic.

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Using the population of 120 individuals for utilization of proposed services, IPM assumes that each individual will require a minimum of twelve visits per calendar year. This estimation of utilization of services is equal to approximately 1,440 patient visits per year for the proposed home care intrathecal management service. The estimation of required visits per year for each consumer is derived from manufacturer recommendations for proper pump maintenance and all aspects of care coordination and is based off of refill intervals, dose adjustments, and monthly assessments of patient status.

IPM estimates a total accumulation of 240 patients by the end of the second year of operation.

ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

IPM's project cost involves the application fee of \$3,000, our first-year office rental expense of \$8738 plus a rental retainer of \$650, office supplies totaling \$500, and an implantable pump programmer for \$800. The total project cost involved is \$134,962.

2. Identify the funding sources for this project.

The proposed project will be funded by cash reserves. A bank statement, balance sheet, and income statement have been supplied (see Attachment C. Economic Feasibility-2.) that evidences sufficient funds.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services Department.

The potential impact to the current health care system in the state of Tennessee is unequivocally positive. If Tennessee is to allow the introduction of the proposed services, the potential benefits are vast. The intended patient population would be offered access to a treatment modality oftentimes not used due to lack of management support. The patient's overall health outcomes would also increase exponentially. IPM's proactive approach allows and encourages early detection of secondary infections that may negatively impact the therapy. In addition to early detection of secondary infections, the program also focuses heavily on patient education and quality of care.

Due to the fact that IPM focuses only on this one therapy, competition from traditional home health agencies is minimal; this is because most traditional home health agencies are not trained, educated, equipped and able to perform this high-tech, niche therapy.

4. Complete Historical and Projected Data Charts on the following two pages.

Please see application.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

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The project's gross operating revenue is projected at \$134,962 for the first year and \$369,562 for the second. Deductions from the gross operating revenue leave the net operating revenue at \$286,500 for the first year and at \$573,250 for the second. Taking into account total operating expenses of \$151,538 for year one and \$203,688 for year two, the net operating income is projected to equal \$134,962 and \$369,562 for the first and second years of operation, respectively.

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing charges.

IPM proposes to charge \$200 per patient visit based on manufacturer recommendations for proper pump care. This rate will be inclusive of the RN refill visit, drug administration, associated wound site maintenance and related pump care, and comprehensive routine patient assessments, and on-call RN Administrator services available 24/7. As we estimate servicing 120 patients during the first year of operation and 240 during the second, at 12 patient visits per year the anticipated gross operating revenue for the proposal equals \$288,000 and \$576,000 for years one and two, respectively.

The average cost per patient is \$100. The average cost per visit is \$200.

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service area, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the current project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

As there are currently no providers in the state of Tennessee specializing in the comprehensive care of high-risk intrathecal infusion therapy, we are unable to provide an accurate rate comparison at this time.

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Each patient is estimated to need approximately 12 visits per year and have an estimated cost of \$200 per visit. With 300 estimated pumps in the state of Tennessee, an expected charge per year would be approximately \$720,000.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

As is evidenced by our projected revenue and expenses, we do not expect to rely on any outside source to cover our expenses. We do, however, have the means by which to do so (please see Attachment C. Economic Feasibility-2.).

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total

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project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

IPM does not anticipate any revenue from the aforementioned sources.

- Range of charges for this type of services by commercial payors: \$150-250.
- Range of Allowable charges covered by Medicare patients: Zero. Medicare does not cover home infusion services. Medicare recipients in need of home infusion services would require a secondary commercial insurance plan to cover intrathecal home infusion.
- 10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

Please see attachment (Attachment C. Economic Feasibility-2.) of IPM's most recent bank statement, income statement, and balance sheet.

- 11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:
- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Since the specific type of therapy which IPM intends to provide is so specialized, and in light of the proven efficacy and superior patient outcomes associated with its total administration in the homecare setting as opposed to outpatient or office visits, IPM has discussed no alternate methods of providing intrathecal infusion therapy.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

IPM's proposal does not include any type of facility construction, and will utilize a rented office space solely for clerical purposes.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g. hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

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Please see Attachment C-Contribution.1. for a list of all Tennessee HHAs currently offering intrathecal home infusion services, which is exactly two. One such agency does not typically provide these services, although able to upon request.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

The proposed intrathecal home care management service will contribute to the orderly development of health care by allowing the affected individuals higher access to quality, specific care while simultaneously working with the patient to optimize therapy outcomes and increasing quality of life outcomes. In many cases, this can result in individuals entering the work force and increasing economic productivity for the individual, thus also for the state.

The economic feasibility of allowing an expert intrathecal pump management company into Tennessee has the potential to greatly reduce overall health care costs to the intended recipients. Utilizing a proactive approach to healthcare has been proven to dramatically reduce overall health care costs. Implanted Pump Management focuses on the patient as a whole, not solely on the implanted intrathecal pump. Utilizing this approach, which is inclusive of comprehensive patient assessments and a high standard of communication between all providers involved in the patient's care, many secondary conditions such as urinary tract infections, falls, skin breakdowns, and or pump therapy failures are thwarted or identified early. Survey results show that this specific approach reduces yearly ER/hospital admissions by over 50%. The intended medical service offers a more cost-effective home management and pro-active nursing assessment that assists the individual patient in achieving a higher level of overall health care, which, in turn, drives the reduction of their cost of care in general (please see graph in Attachment C.Contribution-2 depicting the efficacy of home care over in-office pump management).

The existing health care providers will be limited to neurologists, neurosurgeons, and MDs practicing pain management and/or psychiatry. The specific nature of diagnoses for the intended patient population creates the need for a particular type of medical professional that can participate in the proposed services. The medical professionals that will work with the proposed IPM services are those that have specializations in either pain management or neurology. Listed on the Tennessee Department of Health's website, http://health.state.tn.us/, are over two hundred pain management physicians and clinics currently practicing. Although not all of the aforementioned pain management doctors currently utilize the intrathecal pump, the introduction of the proposed services will allow them the option of expanding their treatment modality.

Although physician reasons for not utilizing the implanted pump to manage pain and spasticity vary, the one most commonly cited is the lack of physician support systems. Implanted Pump Management is, therefore, not only offering the service to the individual patients in their homes, but also to practicing medical doctors. The intrathecal home management program will offer the physicians the avenue for introduction of pump services to their patient population by eliminating the historical burden of care to the physician.

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When utilizing the IPM home care management model, physicians benefit as well as patients. IPM will incorporate a 24-hour on call RN Administrator for patients to utilize with registered nurses and pharmacists at the other end of the phone to answer therapy questions. This is a great benefit for the physicians because they no longer have to supply the support through their individual offices. One of the many goals of IPM is to reduce the time, educational, and financial ramifications of intrathecal pump therapy to physician offices, allowing each physician to focus on quality of care to his/her patients. This approach will increase access to care for patients in the state of Tennessee, who without the IPM home management program might otherwise be denied access to this treatment modality.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for all these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Implanted Pump Management will utilize two full-time RNs during the first year of operation expects to utilize three during its second. We are choosing to pay our RNs an annual salary of \$55,000, which is in accordance with the pay scale as reported by the Bureau of Labor Statistics (see Attachment C. Contribution-3.). We will pay our RN DON an annual salary of \$70,000.

Any contracted infusion pharmacy that IPM has chosen to contract with will hold JCAHO Accreditation and follow all state and federal regulations in regards to intrathecal medications and narcotics. The pharmacy will also follow all 797 Pharmacy standards as regulated by pharmacy law. The compounding pharmacy will be supplied the signed MD order via fax. The compounding pharmacy will then process and compound the medication. The compounding pharmacy will then mail the medication with a copy of the signed order to the primary IPM RN. The signed order will be dated and have all of the following:

Patient Name
D.O.B.
Patient Address
Medication
Concentration
Medication Daily Dose
Volume to be filled

IPM and their RN employees will serve as an "extension to the physician" by implementing strong clinical and assessment skills based on MD orders. The IPM RN will not work out of his/her scope and the Tennessee Nurse Practice Act as stated in the Tennessee Regulatory Statutes. The IPM RN will perform the following: a full nursing assessment, education, and clinical expertise in the intrathecal pump based on signed MD orders. This structure allows the prescribing MD a glimpse of the patient in his or her own environment. Also allowing the RN to witness and identify any changes in ambulation, family dynamics and or unsafe conditions that can all lead the patient to below optimal outcomes. The extension of the RN in the home allows the MD to be aware of findings that could not be witnessed or identified in the MD office

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setting. This approach increases MD awareness of patient needs and services required to obtain optimal outcomes.

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Not Applicable (N/A)

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

Implanted Pump Management has reviewed the aforementioned policies and state requirements and will be able to meet standards outlined by each without issue.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g. internships, residencies, etc.).

Not Applicable (N/A)

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

IPM has reviewed the Rules of the Tennessee Department of Health's Standards for Home Care Organizations Providing Home Health Services and will be able to adhere to all criteria set forth without issue.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure: Tennessee Department of Health (will receive Home Care Organization licensure)

Accreditation: Not Applicable (N/A)

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

IPM is a relatively new company and is actively seeing pts in New Jersey, and just recently JCAHO accredited in the state of Florida. IPM is not Medicare/Medicaid Certified and will not proceed to do so.

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(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Not Applicable (N/A)

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Not Applicable (N/A)

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

Not Applicable (N/A)

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

IPM intends to supply the Tennessee Health Services and Development Agency and any other applicable reviewing agency on behalf of the state any data or information as requested or required.

50 PROJECT COSTS CHART

25		**** *********************************
	50	
	PROJECT COSTS CHART	³⁰ सम् _व देखाः देखाः - व
A.	Construction and equipment acquired by purchase:	82
	Architectural and Engineering Fees	N/A
	 Legal, Administrative (Excluding CON Filing Fee), Consultant Fees 	N/A The State of t
	3. Acquisition of Site	N/A
	4. Preparation of Site	N/A //-
	5. Construction Costs	N/A
	6. Contingency Fund	N/A (A Company of the company of th
30	7. Fixed Equipment (Not included in Construction Contract)	N/A
	8. Moveable Equipment (List all equipment over \$50,000)	N/A
	9. Other (Specify) Programmer and office supplies	1,300,00
B.	Acquisition by gift, donation, or lease:	
	1. Facility (inclusive of building and land)	8,738.00
	2. Building only	N/A
	3. Land only	N/A
	4. Equipment (Specify)	N/A (# 5) (See Fig. 1)
	5. Other (Specify)	
C.	Financing Costs and Fees:	
	Interim Financing	N/A (1907) To Albert (1907)
	2. Underwriting Costs	NAT THE STATE OF STATE OF
	Reserve for One Year's Debt Service	N/A
	4. Other (Specify)	N/A
D.	Estimated Project Cost	10.038.00
D.	(A+B+C)	10,000,00
		3,000.00
E,	CON Filing Fee	13,038.00
F.:	Total Estimated Project Cost	
	(D+E)	
	TOTAL	13,038,00

2.	Identify	the	funding	sources	for	this	project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)
 A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
 B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
 C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
 D. Grants--Notification of intent form for grant application or notice of grant award; or
 ✓ E. Cash Reserves--Appropriate documentation from Chief Financial Officer.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

Other—Identify and document funding from all other sources.

- 4. Complete Historical and Projected Data Charts on the following two pages--<u>Do not modify</u> the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the **Proposal Only** (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).
- 5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

HISTORICAL DATA CHART Not Applicable

G	ive information for the last <i>three (3)</i> years for which co agency. The fiscal year begins in (Month	omplete data	are available	for the facility	/
	(Year	Year	Year	
A.	Utilization Data (Specify unit of measure)				Ŧ
B.	·		×		
	Inpatient Services	\$	I \$[\$	
	2. Outpatient Services				\neg
	3. Emergency Services				╡
	Other Operating Revenue (Specify)				
	Gross Operating Revenue	\$	\$	\$	
C.	Deductions from Gross Operating Revenue				
	Contractual Adjustments	\$	 \$	\$	
	2. Provision for Charity Care				7
	3. Provisions for Bad Debt			1	Ħ
	Total Deductions	\$	\$	\$	
NE	T OPERATING REVENUE	\$	S	\$	
D.	Operating Expenses	-			
	1. Salaries and Wages	\$	 \$	1.8	\neg
	2. Physician's Salaries and Wages				7
	3. Supplies				Ħ
	4. Taxes				\equiv
	5. Depreciation			T .	7
	6. Rent		7		7
	7. Interest, other than Capital			1	
	Other Expenses (Specify)				\exists
	Total Operating Expenses	\$	\$	\$	
E.	Other Revenue (Expenses) - Net (Specify)	\$	\$	\$	\neg
NE	T OPERATING INCOME (LOSS)	\$	\$	\$	
	Capital Expenditures	·			
	Retirement of Principal	S	\$	\$	\neg
	2. Interest	**	77		7
	Total Capital Expenditures	\$	\$	\$	_
NE.	T OPERATING INCOME (LOSS)		10.00		
LES	SS CAPITAL EXPENDITURES	\$	\$	\$	\neg
				U)*8	

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in which the completion of this proposal. The fiscal year begins in which the completion of this proposal.

•			Year 2015	Year 2016
A.	Util	ization Data (Specify unit of measure)	Total # Patient Visits	Total # Patient Visits
B.	Re	venue from Services to Patients		
	1.	Inpatient Services	\$N/A	\$ N/A
	2.	Outpatient Services	288,000.00	576,000,00
	3.	Emergency Services	N/A	N/A
	4.	Other Operating Revenue (Specify) N/A	N/A	N/A
		Gross Operating Revenue	\$ 288,000.00	\$ 576,000.00
C.	Dec	ductions from Gross Operating Revenue		
	1.	Contractual Adjustments	\$ N/A	\$ N/A
	2.	Provision for Charity Care	1,000,00	2,000,00年代,使制
	3.	Provisions for Bad Debt	500,00	750.00
	×	Total Deductions	\$ 1,500,00	\$ 2,750.00
NET	OP	ERATING REVENUE	\$ 286,500,00	\$ 573,250,00
D.	Ope	erating Expenses		
	1.	Salaries and Wages	\$125,000	\$ 180,000
	2.	Physician's Salaries and Wages	N/A	N/A
	3.	Supplies	1,300.00	500.00
	4.	Taxes	1,000.00	1,500.00
	5.	Depreciation	N/A	N/A
	6.	Rent	8.738.00	4.188.00
	7.	Interest, other than Capital	N/A	WANT
	8.	Other Expenses (Specify) OON fee, Health Benefits, Workers Comp	15.500.00	17,500.00
r		Total Operating Expenses	\$ 151,538,00	\$ 203,688.00
E.	Oth	er Revenue (Expenses) Net (Specify)	\$ N/A	\$ NVA
NET	OPI	ERATING INCOME (LOSS)	\$ 134,962 00	\$ 369 562 00
F.	Cap	oital Expenditures		
	1.	Retirement of Principal	\$N/A	\$ N/A
	2.	Interest	NIA	N/A
		Total Capital Expenditures	\$ N/A	\$ N/A
		ERATING INCOME (LOSS) APITAL EXPENDITURES	\$ 104,962.00	\$ 369,562,000

- 6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.
 - B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).
- 7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.
- 8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.
- 9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.
- 10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.
- 11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:
 - a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.
 - b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

- 1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.
- 2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

- 3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.
- 4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.
- 5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.
- 6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).
- 7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.
 - (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure:

Accreditation:

- (c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.
- (d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.
- 8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.
- 9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project
- 10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

- 1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- 2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

Form HF0004 Revised 02/01/06 Previous Forms are obsolete

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as publish	ed in T.C.A. § 68-1	1-1609(c): 11/01/2014
Assuming the CON approval becomes the final agency action from the above agency decision date to each phase of the		
<u>Phase</u>	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed		
2. Construction documents approved by the Tennessee Department of Health		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete	41	
8. Construction 80% complete	•	
9. Construction 100% complete (approved for occupancy		
0. *Issuance of license	0	11/2014
1. *Initiation of service	0	11/2014
2. Final Architectural Certification of Payment		
3. Final Project Report Form (HF0055)		
For projects that do NOT involve construction or renov 10 and 11 only.	ation: Please comp	olete items

Note: If litigation occurs, the completion forecast will be adjusted at the time of the fine

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

Attachment A.3.

STATE OF NEW JERSEY DEPARTMENT OF THE TREASURY FILING CERTIFICATE (CERTIFIED COPY)

Corporation Name:

IMPLANTED PUMP MANAGEMENT LLC

Business Id:

0400475184

Certificate Number:

6000027414

I, THE TREASURER OF THE STATE OF NEW JERSEY, DO HEREBY CERTIFY, THAT THE ABOVE NAMED BUSINESS DID FILE AND RECORD IN THIS DEPARTMENT AN ORIGINAL CERTIFICATE ON February 29, 2012 AND THAT THE ATTACHED IS A TRUE COPY OF THIS DOCUMENT AS THE SAME IS TAKEN FROM AND COMPARED WITH THE ORIGINAL(S) FILED IN THIS OFFICE AND NOW REMAINING ON FILE AND OF RECORD.

IN TESTIMONY WHEREOF, I HAVE HEREUNTO SET MY
HAND AND AFFIXED MY OFFICIAL SEAL AT
TRENTON, THIS
March 14, 2014 A.D.



A. . . .

Andrew P Sidamon - Eristoff State Treasurer

VERIFY THIS CERTIFICATE ONLINE AT

https://wwwl.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF THE TREASURY DIVISION OF REVENUE

CERTIFICATE OF FORMATION

IMPLANTED PUMP MANAGEMENT LLC 0400475184

The above-named DOMESTIC LIMITED LIABILITY COMPANY was duly filed in accordance with New Jersey State Law on 02/29/2012 and was assigned identification number 0400475184. Following are the articles that constitute its original certificate.

1. Name:

IMPLANTED PUMP MANAGEMENT LLC

- 2. Registered Agent: ROY PUTRINO
- 3. Registered Office: 1401 VALLEY ROAD , 4TH FLOOR WAYNE, NJ 07470
- 4. Business Purpose: | IMPLANTABLE PUMP MANAGEMENT
- 5. Members/Managers: ROY PUTRINO 1401 VALLEY ROAD , 4TH FLOOR WAYNE, NJ 07470
- 6. Main Business Address: 1401 VALLEY ROAD , 4TH FLOOR WAYNE, NJ 07470

Signatures:

TIFFANY RUSSELL AUTHORIZED REPRESENTATIVE



Certificate Number 123220260
Verify this certificate online at

Verify this certificate online at https://www.l.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

FILED

FEB 29 2012

STATE TREASURER

LLC

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this

20 4

1st day of March, 2012

Andrew P Sidamon-Eristoff. State Treasurer



STATE OF TENNESSEE Tre Hargett, Secretary of State

Division of Business Services William R. Snodgrass Tower 312 Rosa L. Parks AVE, 6th FL Nashville, TN 37243-1102

IMPLANTED PUMP MANAGEMENT LLC 1401 VALLEY RD WAYNE, NJ 07470-2037

October 24, 2013

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

SOS Control #:

735942

Formation Locale:

NEW JERSEY

Filing Type:

Limited Liability Company - Foreign

Date Formed:

02/29/2012

Filing Date:

10/24/2013 3:13 PM

Fiscal Year Close:

12

Status:

Active

Annual Report Due: 04/01/2014

Duration Term:

Perpetual

Image #:

7252-1309

Managed By:

Member Managed

Document Receipt

Receipt #: 1192779

Filing Fee:

\$300.00

Payment-Check/MO - IMPLANTED PUMP MANAGEMENT LLC, WAYNE, NJ

\$300.00

Registered Agent Address:

CAREY MARTIN

106 OAK SPRINGS LN

RICKMAN, TN 38580-1759

Principal Address:

1401 VALLEY RD

WAYNE, NJ 07470-2037

Congratulations on the successful filing of your Application for Certificate of Authority for IMPLANTED PUMP MANAGEMENT LLC in the State of Tennessee which is effective on the date shown above. Visit the TN Department of Revenue website (apps.tn.gov/bizreg) to determine your online tax registration requirements.

You must file an Annual Report with this office on or before the Annual Report Due Date noted above and maintain a Registered Office and Registered Agent. Failure to do so will subject the business to Administrative Dissolution/Revocation.

Secretary of State

Processed By: Cynthia Dunn

Attachment A.4.

Specializing in The Management of Pain and Spasticity
Implanted Pump Therapies

OWNERSHIP STRUCTURE

Implanted Pump Management LLC (IPM) was formally incorporated in New Jersey on 2/29/12 and filed for authority to conduct business in Tennessee on 10/24/13. IPM is a Single Member LLC owned by Roy Putrino (ownership interest: 100%). Mr. Putrino is a registered pharmacist licensed in New Jersey as well as Tennessee and holds an ownership interest of 70% in Basic Home Infusion, a licensed pharmacy located at 1401 Valley Road, 4th Floor, Wayne, NJ 07470.

IPM intends to employ one Full-Time Registered Nurse (FT RN) during its first year of operation and two during its second; we will also utilize one FT Director of Nursing. These employees will comprise the structure of the company's clinical services to Tennessee residents.

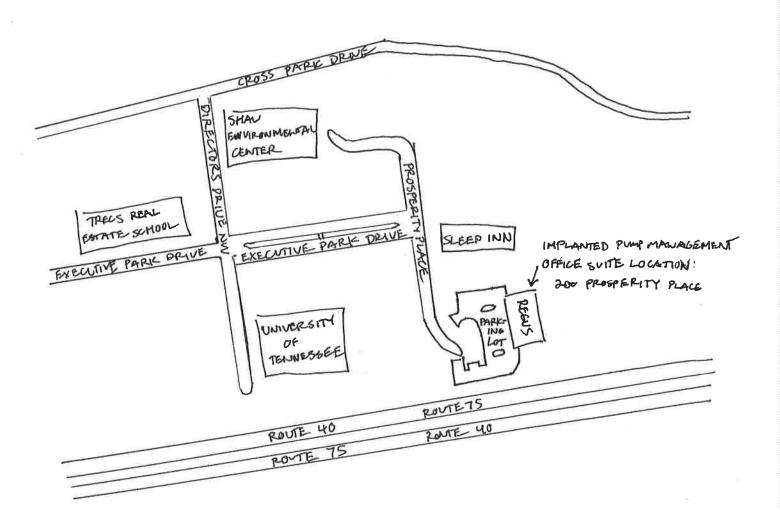
Roy Putrino Owner/CEO Melissa Hess Director of Nursing Field Nurs(es)

Attachment B.3.a.

IMPLANTED PUMP MAN AGEMENT

PLOT PLAN: 6300 PROSPERITY PLACE, OFFICE 102

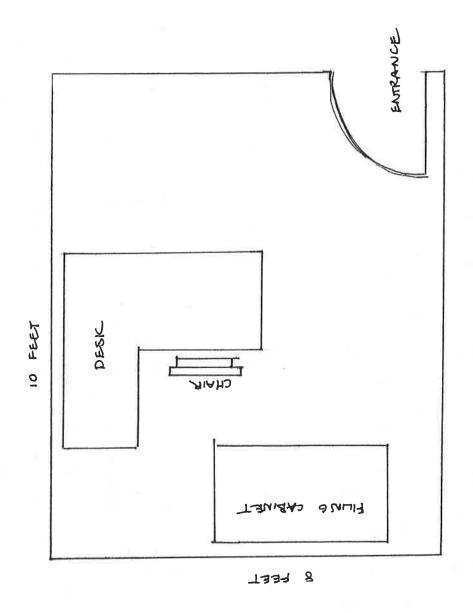
KNOXVILLE, TN 37923



TOTAL ACREAGE = 1.91

Attachment B.5.

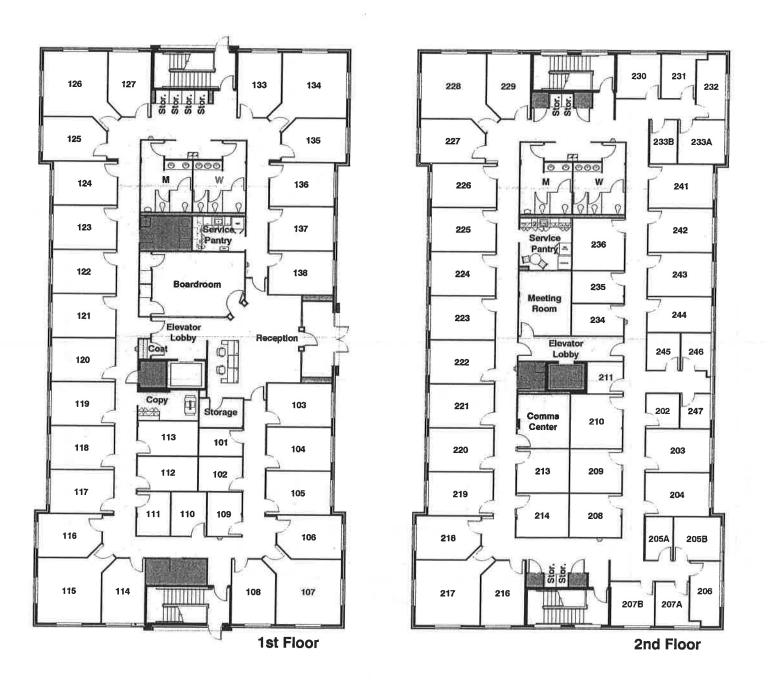
HALLWAY



FLOOR PLAN - OFFICE # 102

HALMAY

TOTAL AREA: 80 SOUARE FEET



Attachment C.Need-1.a.5.Manufacturers.

To Who it may concern,

I am writing this letter to request consideration for allowing for an increase in specialized implanted pump home care services in the state of Tennessee. This service is needed to assist in refilling and managing implanted Intrathecal pumps in patients with spasticity and pain.

Care and management of these devices require detailed, skilled professional services that are best handled by Home professionals trained and focused on the specific task of pump refill and management in order to maximize patient outcomes and safety. Many patients in this population have great difficulty making it to a facility to have their pump managed post implant. This exposes patients to safety risks when appointments are missed. Many patients require the assistance of ambulance and other intensive transfer methods in order to keep refill appointments.

Offering an increase in intrathecal pump home care management will allow for improved quality of life in the spasticity and pain pump patient population. Implant numbers continue to increase and with it, the need for care, refills and education from Intrathecal home care services.

Please let me know if I can answer any questions.

Melisse Hing

Melissa King Smokey Mountains District Medtronic Neurological



Medtronic Neuromodulation 7000 Central Avenue NE Minncapolis, MN 55431 www.medtronic.com phone: 704-718-2875

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Please let me know if I can answer any questions.

Sincerely,

Denny Castillo

Smokey Mountains District

Medtronic Neurological



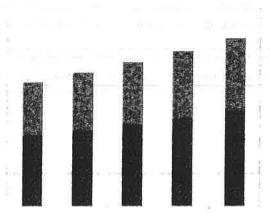
www.flowonix.com
Tel: 973.426.9229
Fax: 973.426.0035
500 International Drive, Suite 200
Mt. Olive, New Jersey 07828

3/18/2014

To whom it may concern,

I am writing this letter to request more intrathecal home care services for the state of Tennessee. We have reached out to Implanted Pump Management to help us with this task.

As a manufacturer, we have seen a steady increase in the number of pumps throughout the country, and our company is expanding the education process throughout the Southeast.



US ASP ≈ \$10,000

OUS ASP ≈ \$7,500

- Two indications Pain (70%) and Spasticity (30%)
- Current U.S. pain market is \$ \$180 million
- Medtronic dominates market with ≥90% share

3

SUC

Please let me know if I can answer any questions.

Sincerely,

Don Donnelly Regional Director Flowonix Medical Attachment C.Need-1.a.5.Patients.

July 24, 2014

To Whom It May Concern:

This letter is written in regards to the need for more home intrathecal infusion services in the state of Tennessee.

I have an implanted intrathecal pump and a homecare option is definitely the best for me and my family.

Please consider allowing more companies to introduce intrathecal home management services to better serve the individuals of Tennessee.

Margaret Stacey
Lebanon, TN 37090

July 24, 2014

To Whom It May Concern:

This letter is written in regards to the need for more home intrathecal infusion services in the state of Tennessee.

I have an implanted intrathecal pump and a homecare option is definitely the best for me and my family.

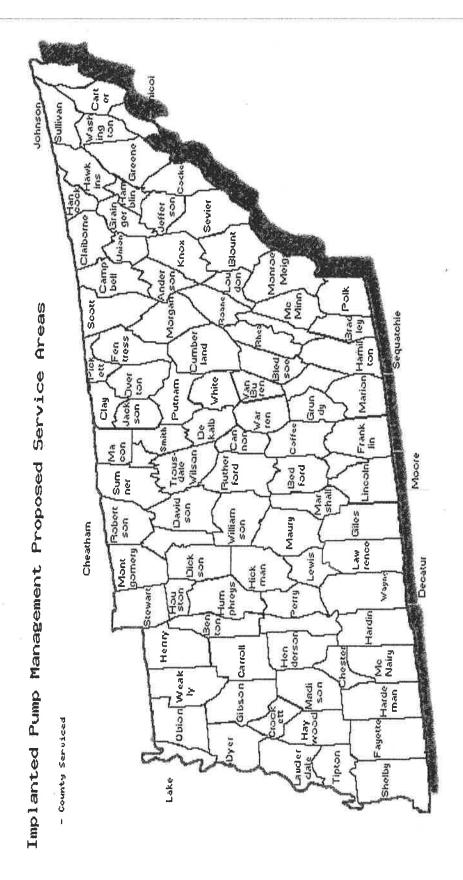
Please consider allowing more companies to introduce intrathecal home management services to better serve the individuals of Tennessee.

Sincerely,

Bom Hent

Bonnie Flint

120 Brookwood Lane Apt 20 Gainesboro, TN 38562 Attachment C. Need-3.



Source: diymaps.net (c)

Attachment C. Economic Feasability-2.

Accrual Basis

IMPLANTABLE PUMP MANAGEMENT Balance Sheet

As of June 1, 2014

	Jun 1, 14
ASSETS Current Assets Checking/Savings	
IPM, LLC - ELECTRONIC VALLEY IPM, LLC - CASH VALLEY	1,445.07 131,069.45
Total Checking/Savings	132,514.52
Total Current Assets	132,514.52
Fixed Assets Accumulated Depreciation Equipment Computer/Phone Software Total Fixed Assets	-7,365.12 29,995.08 16,250.00 38,879.96
TOTAL ASSETS	171,394.48
LIABILITIES & EQUITY Liabilities Current Liabilities Other Current Liabilities Shareholder Loan	102,488.44
Total Other Current Liabilities	102,488.44
Total Current Liabilities	102,488.44
Long Term Liabilities Due to Basic Home Infusion, Inc	9,405.00
Total Long Term Liabilities	9,405.00
Total Liabilities	111,893.44
Equity Retained Earnings Net Income	7,534.80 51,966.24
Total Equity	59,501.04
TOTAL LIABILITIES & EQUITY	171,394.48





IMPLANTED PUMP MANAGEMENT LLC 1401 VALLEY RD

WAYNE NJ 07470-2037

0

Page:

1

Chks Paid: Statement Date: 10 06/30/14

Account Number:

41577485

Indicate to the right any changes of address. Cut at the dotted line and return this form to: Valley Customer Service, 1445 Valley Road, Wayne, NJ 07470

Street:

City, State, Zip:

Signature:

****************** BusinessCHECKING 300

41577485 **************

Checks in Order

Date Number	Amount	Date Number	Amount
06/06 1086	250.00	06/16 1099	89.43
06/13 1087	1,000.00	06/16 1100	622.33
*		06/16 1101	172.14
06/20 1095	120.00	*	
*		06/24 1106	10.60
06/06 1097	250,00	06/24 1107	451.68
06/17 1098	1,557.08	- 1.14 III I	

^(*) Check Number Missing or Check Converted to Electronic Transaction and Listed Under Non-Check Transactions

Daily Balance Summary

Date	Balance	Date	Balance	Date	Balance
05/30	136,339.45	06/16	133,955.55	06/24	131,816.19
06/06	135,839.45	06/17	132,398.47		202,020125
06/13	134,839.45	06/20	132,278.47		

Account Summary

Previous Statement Date: 05/30/14

Beginning			In	terest		Service	Ending
Balance	+	Deposits	+	Paid -	Withdrawals -	Charge	
136,339.45		.00		.00	4,523.26	.00	131,816,19

Statement from 05/31/14 Thru 06/30/14 YTD Interest Paid .00

Report lost or stolen Valley Check Card to: 888-379-9903

800-522-4100 valleynationalbank.com



07/24/14

IMPLANTABLE PUMP MANAGEMENT
Profit & Loss
June 2014

Accrual Basis

Ordinary Income/Expense Income Fee Refunds	125.00
Total Income	125.00
Expense Filing fees Bank Service Charges Insurance Licenses and Permits Printing and Reproduction Rent Telephone Utilities Water	3,000.00 177.01 1,409.48 3,455.00 89.43 1,557.08 342.26
Total Utilities	10.60
Total Expense	10,040.86
Net Ordinary Income	-9,915.86
let Income	-9,915.86

Attachment C.Contribution-1,

Адепсу	Address	Phone Number	Fax Number/Other	Intrathecal home infusion?	# Counties serviced	Health Agency Location
Clinch River Home Health	Clinch River Home Health 401 Sulphur Springs Road, Clinton, TN, 37716	Phone: 865-457- 4263 Phone 2: 865-687- 7070	Fax: 865-457-9415 Fax: 865-687-7040 office@crhh.net	NO		
Home Option by Harden Health Care, The	800 Oak Ridge Turnpike, Suite A208, Oak Ridge, Tennessee 37830	Phone: 865-220- 1700	N/A	ON		
Professional Case Management of Tennessee	800 Oak Ridge Turnpike #100, Oak Ridge, TN 37830	Phone:(865) 481- 4800	N/A	IV Infusion Therapy Only		
Blount Memorial Hospital Home Health Services	1095 East Lamar Alexander Parkway, Maryville, TN 37804	Phone:865-981- 2160	N/A	IV Infusion Therapy Only		
Elk Valley Health Services Inc	5249 Harding Place Nashville, TN 37217	Phone: (615) 360- 1116	Fax: (615) 360-7895	ON		
Quality Home Health		Phone:(865) 531- 0016	Fax: (865) 470-2194	ON		
Amedisys Home Health Care	120 S. Main St. Pikeville, Tennessee 37367	423-447-6841	423-267-9839	NO (IV Only)		
Premier Support Services, Inc	1835 BUFFALO TRAIL MORRISTOWN, TN 37814	Phone: (423) 587- 8771		ON		
Univ. of TN Med. Ctr Home Health/Hospice Service	1924 Alcoa Highway, Knoxville, Tennessee 37920	Phone: (865) 305- 9000		ON		
Amedisys Home Health	5959 S. Sherwood Forest Blvd. Baton Rouge, LA 70816	tel. (225) 292-2031		ON		
Amedisys Home Health Care	230 Cumberland Bend, Suite D, Nashville, TN 37228	Phone: (615) 313- 7400	Fax: (615) 313-7410	ON		
Camellia Home Health of East Tennessee	1700 Liberty St NW, Knoxville, TN 37921	(865) 584-4010		Yes	A lot (wouldn't list)	Knoxville
Covenant Homecare	3001 Lake Brook Blvd., Suite 101, Knoxville, TN 37909	(865) 374-0600		ON		
East Tennessee Children's Hospital Home Health	2018 W Clinch Ave, Knoxville, TN 37916	865-541-8000		ON		
Gentiva Health Services	6223 Highland Pl Way, Knoxville, TN 37919	(865) 584-3133		No		
Gentiva Health Services 2 (Girling Health Care)						
Maxim Healthcare Services, Inc	7417 Kingston Pike #102, Knoxville, TN 37919	865 330 2336		No		
NHC Homecare	9000 Executive Park Dr A205, Knoxville, 37923	(865) 539-0242		ON.		
Tennova Home Health	10820 Parkside Drive, knoxville, TN, 37934	(865) 218-7011		No (Does Home Infusion)		
UTMCK-Home Care Services: Hospice & Home Care	1924 Alcoa Highway, Knoxville, Tennessee 37920	(865) 305-9000		No		
Intrepid USA Healthcare Services	114 S David Lane Unit 11 Parkway Plaza, Knoxville, TN 37922	865-531-1415	865-539-8047	YES (Not many depends on a lot of things) (insurance, severity)	15	Texas
Professional Home Health Care Agency	2221 Jacksboro Pike, La Follette, TN, 37766	(423) 562-6870 (disconnected)				
ANDERSON COUNTY						
Heritage Home Healh	635 N. Main St., Suite D. Shelbyville. TN 37160	931-684-2118	931-685-5355	ON		
Suncrest Home Health	1914 Mcarthur Street, Manchester, TN 37355	(931) 728-2453	4	NO (DO HOME INFUSION)		
Alere Women's and Children's Health, LLC	651 E 4th St Ste 100, Chattanooga, TN 37403-1923	(901) 767-8802		NO		
Angel Private Duty and Home Health, Inc.	333 PLUS PARK BLVD, NASHVILLE, TN 37217-1005	(615) 365-4424	(615) 365-0998	ON		
Careall	4015 Travis Dr #200, Nashville, TN 37211	(615) 835-4445		ON		
Coram CVS Specialty Infusion Services	1828 Midpark Drive, Suite D, Knoxville, TN, 37921-5900	865-450-2380	865.450.2385	ON		
Friendship Home Health Agency	333 PLUS PARK BLVD, Nashville, TN 37217	(615)-365-4424	(615) 365-0998	NO		

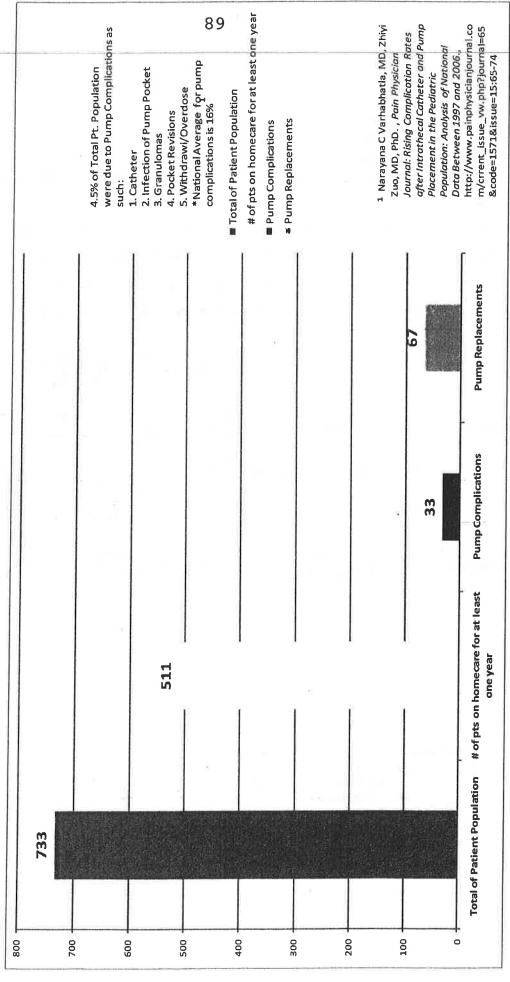
Ноте Care Solutions, Inc.	1410 Donelson Pike B10, Nashville, TN 37217-2952	(615) 874-1423 (DISCONNECTED)			
Willowbrook Home Health Care Agency	3239 Tom Austin Hwy, Springfield, TN 37172	(615) 382-2044		ON	
Caresouth HHA Holdings of Winchester, LLC	2068 Cowan Highway, Winchester, TN 37398	931-967-0633		ON	
Deaconess Homecare	1820 Huntsville Hwy, Fayetteville, TN 37334	(931) 433-2516		ON.	
Lincoln Medical Home Health & Hospice	1797 Wilson Pkwy, Fayetteville, TN 37334	(931) 433-8088		ON	
Suncrest Home Health of Nashville, Inc.	1896 General George Patton 500, Franklin, TN 37067	(615) 591-8089		CN	
Vanderbilt HC Affiliated w/Walgreens IV & RT svcs	500 Wilson Run, Brentwood, TN 37027	(615) 726-0776		NO (IV ONLY)	
BEDFORD COUNTY					
Tennessee Quality Homecare- Northwest	117 Hummingbird Circle, Camden, TN 38320	731-584-2700		NO (IV Only)	
Baptist Memorial Home Care & Hospice	6225 Humphreys Blvd. Memphis, TN 38120	901-227-9000	info.womens@bmhcc .org		
Tennessee Quality Homecare- Southwest	580 Tennessee Ave. North, Parsons, TN 38363	731-847-9228		NO (IV Only)	
Volunteer Home Care, Inc	1875 U.S. 51, Dyersburg, TN 38024	(731) 288-6011		Antibiotic, hydration, TPN (Didn't specify IV vs Intrathecal on site)	
Regional Home Care - Lexington	185 Boswell St. Lexington, TN 38351	Phone 731-968-1860	FAX 731-968-1875	ON	
Henry County Medical Center Home Health	301 Tyson Ave., Paris, TN 38242	Phone: (731) 642- 1220		(Add VI) CN	
St. Thomas Home Health	2000 Church Street, Nashville, TN 37236	(615) 284-5555		ON	
Extendicare Home Health of West Tennessee	90 DIRECTORS ROW, Jackson, TN 38305	(731) 668-1372	(731) 664-9919	NO (IV Only)	
Medical Center Home Health	33 Directors Row Jackson, TN 38305-2316	Phone: 731 984 2000	731.984.2079		
Regional Home Care - Jackson	37 Sandstone Circle, Jackson, TN 38305	Phone 731-668-7143	FAX 731-668-7677	ON	
BENTON COUNTY					
Home Health Care of East Tennessee, Inc	5740 Uptain Road. Suite 6300. Chattanooga. Tennessee 37411	423.510.9010		(Alac VI) ON	
Continucare Healthservices, Inc I		423-386-1000		diam'r.	
Continucare Healthservices, Inc II	1501 Riverside Drive, Suite 350, Chattanooga, TN 37406	Toll Free: 1-800-815- 6264	Toll Free: 1-800-815- info@continucareheal these	al No (IV Only)	
Life Care at Home of Tennessee	7625 Hamilton Park Drive, Suite 16, Chattanooga, TN. 37421	(423) 510-1500	(423) 510-1560	NO (IV Only)	
Memorial Hospital Home Health BLEDSOE COUNTY	3775 Georgetown Rd. NW, Cleveland, Tennessee 37312	423-475-2461	423-472-9457	NO (IV Only)	
Family Home Care - Cleveland	175 24th St NW, Cleveland, TN 37311	(423) 559-6092		NO (IV)	
Guardian Home Care, LLC	3555 Keith St NW, Cleveland, TN 37312	423-473-8886		NO (IV)	
BRADLEY COUNTY					
Home Health Care of Middle Tennessee	Two International Drive Suite 901 Nashville, Tn 37217	615.361.4859	615.361.5187	NO (TEACH ONLY)	
CANNON COUNTY					
Procare Home Health Services	9 Worth Cir, Johnson City, TN 37601	(423) 434-5130			
Johnson County Home Health	1987 S Shady St, Mountain City, TN 37683	(423) 727-3250		NO(IV)	
Medical Center Homecare - Kingsport	2020 Brookside Dr, Kingsport, TN 37660	(423) 392-3510		ON	
AK FK					

Continuous Care Services, LLC	545 Mainstream Dr Ste 100, Nashville, TN 37228	(615) 259-2772 (DISCONNECTED)			
Vanderbilt Home Care Services	2120 Belcourt Ave, Nashville, TN 37212	(615) 936-0336		ON	
СНЕАТНАМ СОUNTY					
Baptist Memorial Home Care & Hospice	631 R B Wilson Drive, Huntingdon, Tennessee 38344	(731) 986-3220		ON	
Home Care Solutions, Inc	242 Heritage Park Dr. #102, Murfreesboro, Tennessee 37129			IV Infusion Therapy Only	
Tennessee Quality Homecare - Southwest	28 East Main Street, Hohenwald, TN 38462	931-796-7149 1-866-385-6423		IV Infusion Therapy Only	
Volunteer Homecare of West Tennessee	313 S Main St, Waynesboro, TN 38485	931-722-6832		Antibiotic, hydration, TPN (Didn't specify IV vs Intrathecal on site)	
NHC Homecare	2100 Park Plaza Dr. Springfield, Tennessee 37172	615-384-0687	615-384-1438	IV Infusion Therapy Only	
Deaconess Homecare II	126 South MAIN St. Oneida, TN 37841	(423) 569-8441	(423) 569-4043	IV Infusion Therapy Only	
Hardin Medical Center Home Health	935 Wayne Rd Ste C, Savannah, TN 38372-1920	(731) 926-8202		NO	
Regional Home Care - Lexington	185 Boswell St. Lexington, TN 38351	Phone 731-968-1860 FAX 731-968-1875	FAX 731-968-1875	ON	
Amedisys Home Health Care	120 S. Main St. Pikeville, Tennessee 37367	423-447-6841	423-267-9839	IV Infusion Therapy Only	
Intrepid USA Healthcare Services	315 West Main Street, Brownsville, TN 38012	731-779-3103	731-779-3104	IV Infusion Therapy Only	
Medical Center Home Health	534 Roland Ave. Jackson, Tennessee 38301	731-422-1100	731-422-4371	IV Infusion Therapy Only	
Regional Home Care - Jackson	37 Sandstone Circle, Jackson, TN 38305	Phone 731-668-7143 FAX 731-668-7677	FAX 731-668-7677	ON	
Careall Homecare Services	1151 Tammbell Street Brownsville, TN 38012	(888) 401- CARE(2273)		IV Infusion Therapy Only	
Chester County Total Licensed Agencies					
Blount Memorial Hospital Home Health Services	175 24th St. NW, Cleveland, Tennessee 37311	423-559-6092	423-559-6093	IV Infusion Therapy Only	
Sunbelt Homecare	149 Healthcare Lane, Jellico, Tennessee 37762	423-784-2452	423-784-1120	IV Infusion Therapy Only	
Amedisys Home Health of Tennessee	230 Cumberland Bend, Suite D, Nashville, TN 37228	615-313-7400		IV Infusion Therapy Only	
Suncrest Home Health & Hospice	1310 East College Street, Brownsville, TN 38012	Tel: 731-772-2655	Fax: 731-772-2695	IV Infusion Therapy Only	
Smoky Mountain Home Health & Hospice	222 Heritage Blvd. Newport Tennessee 37821	423-623-0233	423-623-8311	IV Infusion Therapy Only	
Hancock County Home Health & Hospice Agency	1246 Main Street Po Box 32, Sneedville, Tennessee 37869	(423) 733-4032			
Camellia Home Health of East Tennessee	1700 Liberty St, Knoxville, TN 37921	865-584-4010		IV Infusion Therapy Only	
Covenant Homecare	1615 West Morris Boulevard, Morristown, TN 37813	(423) 492-8100		ON	
East Tennessee Children's Hospital Home Health	11227 W Point Dr, Knoxville, TN 37934			ON	
Tennova Home Health	4127 E. Emory Road, Knoxville, TN 37938	Phone: (865) 545- 3500		IV Infusion Therapy Only	
Claiborne County Total Licensed Agencies					
Cumberland River Homecare	100 Old Jefferson Street, Celina, TN 38551	931-243-3680	800-382-3341	IV Infusion Therapy Only	
Brookdale Home Health Nashville	4538 TROUSDALE DRIVE, NASHVILLE, TN 37204	(615) 598-9662		IV infusion Therapy Only	
Coram CVS Specialty Infusion Services	2970 Sidco Drive, Nashville, TN 37204-3715	615.445.3098		Al	
Highland Rim Home Health Agency	337 N. Cedar Ave. Cookeville Tennessee 38501	931-528-5578		N.	
Clay County Total Licensed Agencies					
Advanced Home Care, Inc.	1012 Coolidge St. Greeneville, TN 37743	423.783.6500		2	
Laughlin Home Health Agency	228 N. Main St. #7 Greenville Tennessee 37745	423-787-5000	423-636-2633	2	
Cocke County Total Licensed Agencies					
					_

Angel Private Duty and Home Health, Inc.	333 PLUS PARK BLVD, NASHVILLE, TN 37217-1005	Phone (615) 365- 442		ON	
Vanderbilt Community & Home Services	1211 Medical Center Drive, Nashville, TN 37232	(615) 322-5000		(A INO AI) ON	
Caresouth HHA Holdings of Winchester, LLC	2068 Cowan Highway, Winchester, TN 37398	(866) 291-3017		ON CASE	
Lincoln Medical Home Health & Hospice	1797 Wilson Pkwy Favetteville. TN 37334	(931) 433-8088			
Friendship Home Health, Inc.	333 Plue Park Blvd, Nashville, TN 37217	(615) 365-4313			
Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	500 Wilson Pike Cir, Brentwood, TN 37027	(615) 726-0776		NO IV ONLY	
Coffee County Total Licensed Agencies					
Baptist Home Care & Hospice - Covington	REPEAT 1618 U.S. 51, Covington, TN 38019	(901) 476-0333		A INO ALON	
Crockett County Total Licensed Agencies					
Quality Home Health	117 Hummingbird Circle Camdon Tonnescoe 38220	OOFC 102 10T	7000 801 801		
Quality Private Duty Care	9333 Park West Blvd Ste 105a , Knoxville, TN 37923-4305	(855) 531-0016	/31-584-3866	NO (IV ONLY)	-
Cumberland County Total Licensed Agencies		oto to loo		2	
Gateway Home Health Clarksville	1750 Marking Ct. Producting T				
lifeline Home Health Care	2400 Ball of ClarkSville entressee 37043	931-648-4576	931-920-6100	NO (IV ONLY)	
Meritan Inc.	A700 Booler Avenue Suite 400 Manual TR 20012	(615) 384-4644		ON	
Highpoint Homecare	ESE Harteville Bibs Collette TN 22006	(301) /66-0600		ON	
Guardian Home Care of Nashville, 11C	COOLEG CAME TING CONGENITY IN STOOM	2899-825 (CID)		ON	
Davidson County Total Licensed Agencies		0807-1//510		NO (IV ONLY)	
American National Home Health	95 Signature Pl, Lebanon, TN 37087	(615) 453-1029		OX	
DeKalb County Total Licensed Agencies					
Regional Home Care - Dyersburg	1937 Cook St. Dversburg. TN 38024	7050-786 (1554)		(XINO III) ON	
Methodist Alliance Home Care	6400 Shelby View Dr #101, Memohis, TN 38134	(901) 516-1999		NO (IA CINET)	
Baptist Home Care & Hospice - Covington	1618 U.S. 51, Covington, TN 38019	(901) 476-0333			
Dyer County Total Licensed Agencies		corp of the the		2	
Where the Heart is	760 Great Oaks Rd, Eads, TN 38028	(901) 867-1556		ON	
Accredo Health Group, Inc	1640 Century Center Pkwy #110, Memphis, TN 38134	(901) 385-3600		ON	
Baptist I rinity Home Care	6141 Walnut Grove Rd, Memphis, TN 38120	(901) 767-6767		NO (IV ONLY)	
best Nurses inc.	6061 Apple Tree Dr, Memphis, TN 38115	(901) 797-9111		ON	
Family Home Health Agency	TO ADD MT SHamman A work own by PAT	(901) 575-8750			
Functional Independence Home Care, Inc	270 German Oak Dr. Cordova TN 38018	DISCONNECTED		0.7	
Home Health Care of West Tennessee Inc	2005 ADDING BO CHITE 402 Bootlett TA 20122	0400-000/100/		2	
Homechoice Health Services	1310 F College St. Brownsville TN 32012	(800) 824-81/4		ON C.	
Interim Healthcare of Memohis. Inc.	2620 Thousand Oaks Blud Suits 1400 Massacht TN 20110	(201) 4/0-2411	1000	0	
No Place Like Home, Inc	354 New Byhalia Rd. Collieville TN	(501) /BI-5000	(901) /6/-09/2	ON C	
Fayette County Total Licensed Agencies		6666-660 (+05)		O _K	
Maury Regional Home Services	830 Hatcher Ln. Columbia. TN 38401	(931) 490-4600		CZ	
Quality First Home Care	500 S James Campbell Blvd. Columbia. TN 38401	(931) 540-0062		0 0	
Giles County Total Licensed Agencies	doctor of the state of the stat	2000-040 (400)		02	
Hometown Home Health Care Inc.	121 Forest Hills Rd, Rogersville, TN 37857	(423) 272-7941		NO (IV ONLY)	
Greene County Total Licensed Agencies					

Magnolia Regional Health Care Home Hospice	2034 E Shiloh Rd, Corinth, MS 38834	(662) 293-1405		ON	
Hardin County Total Licensed Agencies					
Sweetwater Hospital Home Health	304 Wright Street, Sweetwater, TN 37874	(865) 213-8508		ON	
Loudon County Total Licensed Agencies				ĭ	
Regional Home Care Parkway					
Obion County Total Licensed Agencies					
Americare Home Health Agency, Inc	3949 Whitebrook Dr, Memphis, TN	(901) 345-5853		(NO ANSWER)	
Still Waters Home Health Agency	856 Willow Tree Cir, Cordova TN	(901) 794-7988		ON	
Shelby County Total Licensed Agencies					
Unicoi County Home Health	100 Greenway Cir, Erwin, TN 37650	423 431 6146	(423) 743-1244	NO	
Unicoi County Total Licensed Agencies					
At Home Healthcare	4711 Trousdale Drive, Suite 129, Nashville, TN 37220	615.988.2604	615.891.4326	ON	
Williamson County Total Licensed Agencies					

Attachment C.Contribution-2.



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AFFIDAVIT

STATE OF New Jersey

COUNTY OF Passaic

Roy Putrino being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, et seq., and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

SIGNATURE/TITLE

Sworn to and subscribed before me this 25 day of

a Notary

Public in and for the County/State of Now Town

ARY PUBLIC

My commission expires

(Month/Day)

2015 (Year)

23

MARILYN MCGRATH Notary Public State of New Jersey Commission Expires Jul 11, 2015

SUPPLEMENTAL #1

IMPLANTED PUMP MANAGEMENT CON Application Supplemental Responses

5. Section B, Project Description, Item I

Please provide responses for each item that follows:

A. As the applicant is aware, Home Health Agency services (HHA) are regulated under Tennessee statue (TCA 68-11-201). Please provide a description of the types of services defined under the statute that apply to this project such as skilled nursing care, medical social services, and medical supplies/medical appliances and the admission criteria that must be met for patients to qualify for admission to the proposed HHA. In your response, please discuss the duties, functions and tasks which the applicant intends to perform as part of its intrathecal home infusion program giving examples of services provided by the applicant in other states.

The type of services provided by the proposed HHA would be skilled nursing services and infusion services. IPM plans to adhere to and practice all TN statutes dictated for the proper administration of a Home Health Agency. Each individual will be admitted based on need, financial viability, and clinical appropriateness. IPM will perform a full nursing assessment upon every patient contact, full intrathecal pump evaluation, and implement any MD orders involving the intrathecal pump management. Not only will IPM implement MD orders in regards to the intrathecal pump, but IPM will also utilize the existing HHAs in the state to refer individuals for additional services not in IPM's scope of practice.

B. Should a patient served by Implanted Pump Management require home health services for conditions other than those related to the intrathecal home infusion products, how does the applicant intend to respond to these needs across all counties of Tennessee based on a staff of one registered nurse in Year 1 and two RNs in Year 2? Will these services be provided directly or will the applicant seek to refer the patient out to another licensed home health agency to provide the care not related specifically to the infusion service?

IPM will utilize the existing Licensed Home Health Agencies in the state of Tennessee for any services outside of IPM's intrathecal pump management. IPM intends to establish working relationships with the local HHAs to determine their individual scope of practice to determine the best pathway for each individual. IPM will refer the individual to the appropriate licensed HHA that best fits that individual's medical needs. IPM will employ a Director of Nursing (DON), who will also function as Administrator, as well as an additional RN for the first year of operation. During the second year of operation, IPM will utilize one additional RN so that three Full-Time Employees (FTEs) sufficiently provide coverage through the entire state.

C. Please define specific types of services patients are likely to require and discuss what special needs and care the patient and/or caregiver will require to provide for quality patient care. As an example, services for skilled nursing care may include, but not be limited to any of the following: (1) take & record patient vital signs (2) draw blood and other fluids for lab (3) treat any issues associated with access site or port and (4) check line and pump function in accordance with practice guidelines.

Patients with intrathecal pumps will receive a comprehensive nursing assessment with each visit consisting of a complete set of vital signs, determination of pain and / or spasticity level, head to toe assessment of all systems within the body, and a telemetry reading of the pump in accordance with practice guidelines. Intrathecal therapy does not involve any wound care or blood/fluid draws for lab.

D. Please clearly identify the responsibilities of the patient's physician, any pharmacists affiliated with the service (including compounding pharmacy, if applicable), the home health agency (including administrator, director of nurses and home infusion RN), and any others associated with the care of the patient for intrathecal home infusion services. Please describe how the proposed intrathecal home infusion service will complement and contribute to the degree of physician oversight for the patient.

The MD responsibilities will not change for the individual patient with the introduction of the proposed service. The addition to IPM will only relieve some of the burden of the intrathecal pump management for the MD. The MD will still be responsible for seeing the patient in his/her office as needed. The MD will still be required to actively participate in the writing of orders and be available for IPM if concerns or abnormal findings are present. The proposed service will:

- 1. Decrease MD workload and staff requirements for office staff
- 2. Eliminate the procurement of intrathecal medications for refills
- 3. Eliminate liability for inaccurate pump refills or programming
- 4. Eliminate tracking of alarm dates for patients by the MD
- 5. Reduce overall workload of MD office in regards to the intrathecal pump patients

The HHA or IPM will be responsible for:

- 1. Full nursing assessments and the required reporting of any abnormal findings
- 2. Monitoring and tracking all alarm dates
- 3. Coordination of services for patients
- 4. Contracting with Infusion pharmacies for intrathecal medications
- 5. All aspects of billing
- 6. Maintaining all required polices and procedure for HHA licensure in the state of TN
- 7. Education and training for patients and staff
- 8. Maintaining all administrative functions for the HHA licensure

The proposed model from IPM will increase physician expertise and awareness of the patient by offering the MD an insight of the individual's home environment, dynamics, and available support systems. This model closely mimics many principles of telemedicine. Instead of the MD only seeing the patient for refills and focusing on that task, the MD will not get documentation complete with pictures of the whole patient.

E. The applicant notes that Tennessee has other companies that offer infusion therapy services that oftentimes offer minimal services of home infusion therapy management but none that specialize in intrathecal home infusion services. Please identify these agencies and discuss the reasons why this is so. Has the applicant collaborated with these HHAs to identify, measure and otherwise assess the need for its services? Please describe the applicant's planning and research efforts in this regard in preparing for the development of its certificate of need application.

IPM has not collaborated with other licensed HHAs that might offer this service. Due to the nature and the specificity of this therapy, the best approach is a sole focus. Therefore IPM proposes the intended service to be the only provider in the state of Tennessee that focuses solely on intrathecal home management. IPM does not intend to offer any other services than those related to intrathecal home care management. The planning and research for the proposed project was derived from the physician and manufacturer response for a qualified, sole focus provider to be available to the patient population in Tennessee.

F. What insight or expertise has the applicant sought from members of the medical community, including the physicians that provide intrathecal pump infusion services in Tennessee, existing nation-wide providers of intrathecal services, the Tennessee Medical Association, Tennessee Hospital Association and others? Why haven't these arrangements worked and how will the creation of another agency improve coordination and quality of care?

IPM has sought insight from multiple providers in the state of Tennessee as well as the two main manufacturers of implantable intrathecal pumps in the country. Currently based on the feedback from both the physicians and manufacturers there is an insufficient support system available in the state of Tennessee for intrathecal homecare management. It is important to delineate the difference between "home infusion services" and "intrathecal home infusion management." Home infusion services can range from simple hydration, antibiotic regimes, and TPN, are just a few examples. The before mentioned therapies have a definite ending point based on MD orders. Intrathecal homecare management is a totally different type of "home infusion." The therapy is complex based on the location of delivery (the intrathecal space), the acuity is very high and it is a lifetime therapy. An individual whom receives an implanted intrathecal pump will have that pump for the duration of that individual's lifespan. The

difference in this type of treatment modality is huge in regards to the management and care required for these individuals. IPM recognizes that these individuals are patients for a lifetime and therefore IPM has created a holistic approach to intrathecal management that fosters and focuses on education, a pro-active approach, and a therapeutic relationship with the ordering MD. This approach assists the MD and patient to obtain the most optimal results with this treatment modality. The overall result with the proposed intrathecal homecare management model is to improve and facilitate coordination and quality of care.

G. The applicant is proposing a statewide, topographically diverse service area covering all rural and urban Tennessee counties. Discuss how the applicant 's 1 registered nurse intends to service approximately 120 patients representing 1,440 RN visits in Year One statewide from a single location in Knoxville focusing on a 48 hour response time?

The statewide topographical region that IPM proposed to cover is vast, but with the proposed service model, IPM will be able to safely and effectively cover the proposed area. This will be done by utilizing one FTE (Registered Nurse) for every 40 to 50 patients. Each FTE will be responsible for an area of 180 miles radius of that FTE's home address. Throughout the 180 miles radius that FTE will be responsible for between 40 to 50 patients. At the time when the identified RN has reached their max patient census, another FTE will be utilized for the next 40 to 50 patients. The FTEs will be hired and sought after based on geographical location to best ensure the 180-mile radius is utilized. When IPM reaches the intended or goal number of a census of 120 patients, the FTE needs will be 3 FTEs (registered nurses). Each FTE will be located physically as close as possible to their 180-mile radius of patient census. This structure will allow for optimal state and patient coverage and allow for the 48-business hour response time for any titration or patient requests.

H. What is the applicant's operational delivery model as it pertains to the overall process of care for patients receiving intrathecal home infusion services? In your response, please discuss the intrathecal home infusion product delivery methods, service coordination with physician and pharmacists, and patient supervision and care coordination provided by the home health agency's infusion nurse.

IPM's delivery model is able to deliver all aspects of intrathecal home management to the recipient in the comfort of his/her home. IPM will coordinate with the ordering MD all RN assessments, telemetries, and pump findings upon every patient encounter. IPM will contract with a licensed infusion pharmacy for the required and MD ordered intrathecal medications. IPM will provide to the individual patient refill services, required medications, RN programmers to read and program the implanted pumps, full nursing assessments that identify any abnormal findings, and required education to the patient and family members and/or caregivers involved. The education piece ranges from home care safety, i.e. throw rugs increases risk for falls with individuals with

mobility issues, to identifying and demoing the intrathecal pump alarms so that each patient understands the pump. The goal of IPM in regards to patient engagement is to encourage education at every encounter and to increase patient active involvement in his/her healthcare. IPM feels that a well-informed and educated patient can better actively take a role in his/her own healthcare. IPM will also encourage and facilitate strong involvement from the ordering physician. IPM is but an extension of the MD's office to deliver quality and expert home intrathecal services. IPM will communicate via a 24-hour web portal that allows each MD to access patient information in "real-time" to monitor patient and RN encounters. IPM will also contact the ordering MD if any abnormal findings are found at any patient encounter. This communication will be made via emailed progress note or phone call based on importance and urgency of the identified "abnormal finding." The IPM RN will be responsible for maintaining and fostering a therapeutic relationship not only with their patients, but also with their prescribing MDs. RNs will also make scheduled visits to their ordering MDs from their patient census to deliver notes, required communication and or for open discussions regarding patient care. The entire proposed delivery system encourages communication, education and ensures quality of care.

- I. Please provide brief descriptions of the following: (1) how potential diversions will be handled such as those that could involve the loss or theft of controlled substances; (2) the level of physician involvement in the provision of services to the proposed home health agency's patients; (3) the technology to be used to facilitate the nursing service across the entire state such as the proposed HHA's participation in a telemedicine network with state-wide coverage; and (4) the interaction with the ordering/supervising physician especially as it relates to support for the care of these patients.
- 1. Potential diversions will be handled per IPM policy and procedure. In the event that a loss or theft of a controlled substance occurs, the IPM RN will alert the Administrator and Pharmacy of the occurrence. IPM will alert the appropriate officials (local authorities) in the event of a theft. The contracted pharmacy will be alerted of the need for an additional syringe for the patient and a new MD order will be obtained. Each RN will take steps per IPM policy for locked storage of medication and safety for the RN.
- 2. The level of the physician involvement is completely dependent on the signed orders that IPM will receive from the ordering physician. IPM only provides intrathecal home management, but that being said, IPM will only implement patient encounters with a signed MD order. Essentially IPM will perform no function without signed MD orders.
- 3. The technology used to facilitate ease of care and continuity of care is as follows:
 - A customized neurological and pain assessment proprietary to IPM
 - A secure Web portal that allows for 24 access to both physician and patient access to all records, signed orders, RN assessments, telemetries and any pictures of abnormal findings

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• 24-hour on call and emergency access to RN administrator for patients, physicians and RNs.

- 4. The physician interaction with the care of the intended patients is implicit on the success of the proposed service model. IPM will only implement orders from the ordering MD. IPM will act as a resource to both the ordering MD and the patient, but IPM is only an extension of the ordering MD office. Therefore the physician involvement must be present and constant for success of the model and the patient outcomes.
- J. Please discuss how the applicant intends to develop, manage, implement, supervise and maintain patients' plans of care, including plans to manage patient pain.

IPM will develop, manage, and implement and supervise a customized patient plan of care based on the services provided by IPM. Based on the disease process and underlying reasoning why the individual has an intrathecal implanted pump, IPM will create a customized care plan tailored to the intrathecal pump therapy. The plans of care will be generated and reviewed on a sixty-day basis and signed and approved by the ordering MD. Pain control and management will be individually discussed with each individual whom suffers from pain. The implanted intrathecal pump will many times assist and or eliminate chronic pain. The individual will be educated on the 24-hour number to call for any quick or unusual changes in pain and also for any potential signs and symptoms of drug over/under-dosing. IPM will work in collaboration with the ordering MD with the set pain goals for that individual.

K. Who mans the 24 hour call center referenced in the application's description of services? Does the applicant have any plans to combine the call center with a telemedicine type service for home health patients?

The DON/Administrator, who has over 9 years of experience in this specific therapy, is the sole individual responsible for the administration and implementation of the 24-hour call center.

L. What is the specific staff training/experience to be required for this type of service as it applies to clinical staff (RNs/DON), the administrator and 24 hour call center staff of the proposed HHA?

The required training for the RN's/DON and administrator is as follows:

- Each RN must hold an active RN license in the state of practice with no deficiencies or actions
- Each RN must have at least two years of RN experience prior to this position
- The DON must have graduated from a Bachelors of Science of Nursing Program in good standing
- The DON must have had at least one-year supervisory experience prior to holding the position

- Each RN/DON must have completed the required manufacturer training including theory, clinical and practical successfully
- The 24 Hour call Staff RN must have documented training including theory, clinical and practical successfully

6. Section B, Project Description, Item II.A.

The applicant states that the development of the proposal includes a 30 day postlicensure initiation. Since the earliest the application could be heard is at the September 24, 2014 HSDA meeting, it appears that a 6 day turnaround time to achieve licensure is highly unlikely. Please clarify. In your response, please reconsider the dates entered in the Development Schedule, revise and submit a replacement page with the schedule, as necessary.

Taking into account the September 24th review date for the Health Services and Development Committee, Implanted Pump Management (IPM) proposes November 1st of 2014 as our projected initial decision date.

The applicant also states that it has staff, contracted services and physician providers in place waiting for the proposed service to be approved. While it is understood that the applicant plans to utilize a registered nurse, the nature & scope of the contract services & physician provider support should be described in more detail. The availability of these resources should also be documented in other sections of the application such as Section C, Need and Economic Feasibility, as applicable.

IPM will employ one full-time nurse and one full-time Director of Nursing (DON), also to act as Administrator, to service all 95 counties. These RNs have already agreed to job proposals and are able to commence full-time employment upon the projected decision date. These full-time employees will cover all aspects of skilled nursing services provided to patients. IPM intends to employ one additional full-time RN during its second year of operation.

IPM intends to utilize contracted infusion pharmacy services. These services will be ready to be utilized upon our projected initial decision date. The following services will be inclusive within our pharmacy services contract: medication compounding, processing of medication orders, dose titrations and changes, and patient medication counseling.

The RN DON/Administrator, with over 9 years of experience in this specific therapy, will provide 24/7 on call and emergency services. This will assist in facilitating efficient communication between IPM nurses, patients and the patient's physicians or prescribing provider. In this manner, IPM will ensure optimal patient care and provider support.

7. Section B, Project Description, Item II.C.

The response is noted. In your discussion, please confirm any limitations to the service such as the applicant's plans to limit the proposed HHA to the provision of intrathecal home infusion services only. In your response, please also briefly discuss the following:

How will the applicant meet the needs of home infusion better than the existing process? Better coordination of administration, better trained nurses? From the applicant's experience, please provide an estimate of the additional health care delivery cost savings, such as elimination of hospital stays, outpatient visits, etc, which could be realized by initiation of this new service

From the applicant's experience, please discuss how the proposed service will safeguard against potential errors, such as medication errors that could result in serious harm or death. Please also briefly describe how the applicant will implement and maintain safeguards to prevent loss or theft of controlled substance medications used in the course of treatment for the intrathecal home infusion service.

The limitations to the proposed services are strictly limited to intrathecal home management services. IPM intends to offer no other services than those required for home intrathecal pump management.

a. The proposed model will better meet the needs of the intended individuals better than the existing process by the following;

a. Offering expertly trained RN's and pharmacists to monitor and assist

the physician in the therapy

b. Offering the patient a full home based assessment not only focused on the pump to quickly identify a potential problem i.e.: changes in skin integrity or urinary tract infections

c. Offering the patient and caregiver/family to become actively involved

in a home care setting fostering the learning potential

d. Offering education and training to the patients and care givers at every RN /patient encounter

e. Establishing an extension of services to the ordering MD to increase encounter and facilitate assessment findings

f. The model mimics tele-medicine

- b. Based on the successful implementation of the proposed model in other states. This model will:
 - a. Eliminate and or greatly reduce ER visits for pump related complications
 - b. Reduce secondary infections such as UTI's or skin breakdowns by early identification
 - c. Increase the patient quality of life with a goal to return to work force, and or mainstream schooling
 - d. Greatly reduce hospital stays as a result of potential pump problems or knowledge deficits of hospitals in regards to this treatment modality

c. The proposed service will safeguard against potential errors by:

a. Implementing a triple check system upon receiving MD ordered syringes for this treatment

b. Utilizing the RN Administrator as a double check system for RN's in the home when advanced programming is required

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c. The home RN will double check the telemetry at the end of each visit with the patient prior to leaving the patient home to identify any potential programming errors

d. The home RN will review the syringe label with the patient and or caregiver and identify: Pt. name, drug, concentration and daily dose

ordered.

e. The home RN will be instructed on the refill process and if all safety checks are not present, the RN will not continue the refill for safety. MD will be notified and RN will take direction from MD for refill

Section B, Projection Description, Item III (Plot Plan) and Item IV (Floor Plan)

Please provide these items as requested.

Please see Attachment B.3. (Plot Plan) and Attachment B.4. (Floor Plan).

Section B, Project Description, Item V (Home Health Agency)

Item 2- the response must identify the proposed service area.

IPM intends to provide intrathecal home infusion services to all 95 counties within the state of Tennessee, listed as follows: Anderson, Bedford, Benton, Bledsoe, Blount, Bradley, Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, DeKalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putnam, Rhea, Roane, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, Wayne, Weakley, White, Williamson, Wilson.

Item 3 – Please provide a description of the Knoxville home office including its size (e.g. ability to accommodate staff of the HHA and a 24-hour call center) and cost as compared to commercial office rental space. In your response, please also discuss the operation of the 24-hour call center including staffing (salary/ wage personnel or contract service) and the call center's primary means of communication with patients and attending physicians. Will call center personnel work on-site or at a remote location (if off site, please specify site address)? Please clarify.

Our office location at 200 Prosperity Place in Knoxville, TN is 8' by 10' (80 square feet total). This space is comparable in cost to other similar office rentals in Knoxville (please see our rental agreement and addendum in Attachment B.5.Item 3.). This space is large enough to accommodate one nurse and all necessary office supplies, i.e. desk,

computer, telephone, locked filing cabinet, nursing supplies, etc. The office will never be occupied by more than one RN simultaneously.

Regarding 24-hour emergency and on call services, these will be provided by a single RN DON/Administrator with over 9 years of experience in intrathecal therapy. (IPM may choose to contract for call center services in order to provide emergency and on call care at a future date when it is within our budget.) Contracted pharmacy services will be provided by staff at a remote location.

Item 4 –Please explain the rationale for a parent office without any branch offices located in the applicant's proposed 95 county state-wide service area. In your response, please address how this complies with existing HHA licensing requirements such as might apply to branch offices centrally located within a 100 mile radius of service area population in distinct geographic areas, within specific driving times or distance requirements, and proximity to access to a sufficient workforce such as nursing staff for skilled nursing services, etc.

Due to the nature of intrathecal infusion therapy whereby our RNs visit patients intermittently on average over a long period of time to perform refills, we are able to offer comprehensive coverage of our services across the entire state of Tennessee by employing two full-time employees to provide skilled nursing services during our first year of operation. We project that the number of FTEs will increase to three by year two. Our administrator, who will also be employed as one of the full-time RNs, will utilize our home office. It will not be necessary for our other employed nurses to utilize branch offices, nor will we have a need to utilize a branch office for any other function—pharmacy services—as contracted professionals will provide these at a remote location.

At a rental rate of \$325 per month, please describe how the applicant's parent office at 200 Prosperity Place in Knoxville, TN can accommodate assigned nursing staff, a director of nurses, an administrator, 24 hour on-call staff, and provide privacy for meetings or conferences with patient caregivers, invited guests and other members of the general public.

Absolutely no patients, caregivers, or physicians will ever be visiting the home office for conferences or meetings as all necessary communication will take place either over the phone (directly with IPM nursing staff or via contracted pharmacy call center) or within the comfort of a patient's home or other location as designated convenient for the patient. Regarding on-call and emergency services, these will be rendered in the same fashion—the home office will be utilized solely for administrative purposes.

10. Section C, Need, Item 1 (State Health Plan)

Tennessee Code Annotated Section 68-11-1625 requires the Tennessee Department of Health's Division of Health Planning to develop and annually update the State Health Plan. The State Health Plan guides the state in the development of health care

programs and policies and in the allocation of health care resources in the state, including the Certificate of Need program. The <u>5 Principles for Achieving Better Health</u> form the State Health Plan's framework and inform the Certificate of Need program and its standards and criteria.

Please discuss how the proposed project will relate to the <u>5 Principles for Achieving</u>
<u>Better Health</u> found in the State Health Plan. Each Principle is listed below with example questions to help the applicant in its thinking.

- 1. The purpose of the State Health Plan is to improve the health of Tennesseans.
- a. How will this proposal protect, promote, and improve the health of Tennesseans over time?

The proposed service model will protect, promote and improve the health of Tennesseans over time by creating a proactive option for intrathecal home care management. The models overall goal is better outcomes, access to care and quality clinical management of the intrathecal pump. This goal can only assist in improving the quality of life of the Tennesseans whom can utilize this service.

b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?

The health outcomes that will be impacted are potentially vast:

- Reducing ER and hospital visits for the Tennesseans utilizing the proposed services
- Increasing quality of life and promoting return to the work force
- Reducing secondary infections by early interventions
- Allowing utilizing MD's a chance to offer this therapy to more Tennesseans, as a management home program will be available

IPM will use surveys and a quality assurance program to measure the date required to prove the goals listed above. The data derived from surveys and patient utilization from insurance carriers will be collected and provided to the state of Tennessee if requested.

c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?

IPM will use surveys and a quality assurance program to measure the date required to prove the goals listed above. The data derived from surveys and patient utilization from insurance carriers will be collected and provided to the state of Tennessee if requested.

- 2. Every citizen should have reasonable access to health care.
- a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.

The intended proposal will increase or improve access to health care by allowing the physicians practicing in the therapy to implant more. Historically with this therapy if a MD utilized the intrathecal pump there is a large burden of care for the ordering physician. Because the pumps are a lifetime therapy across the country many physicians have stopped implanting intrathecal pumps purely based on the burden of care. Utilizing the proposed model, IPM almost eliminates the burden of care for the MD and greatly decreases the burden of care on the individual patient. The MD will now be able to actively manage more patient's implant more and not face that dreaded "married to the pump "mentality. This model will actually serve as increasing many Tennesseans access to care for intrathecal pumps.

b. How will this proposal improve information provided to patients and referring physicians?

The proposed model will improve the nature of information to the patients because of the heavy focus on education and active involvement. The referring physicians whom utilize this service will be given quality, clinical information in regards to this therapy and patient encounters in real time. The MD's will be able to follow their patients on the secure Web portal and stay actively involved during every patient encounter. This model will actually increase MD involvement.

c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?

The health literacy and exchange of information between patient and provider will be facilitated through the 24 Hour call center. The 24-hour on call nursing Administrator will work hard for both the patient and the prescribing MDs. The 24-hour on call nurse will be a resource to the patients and also to the MDs facilitating quick and accurate notifications to the MD and education to the patients.

- 3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.
- a. How will this proposal lower the cost of health care?

This proposal will effectively lower the total healthcare costs to those utilizing the system. By reducing ER, hospitalizations, and secondary infections with IPM's proactive approach, the overall healthcare costs will be reduced.

b. How will this proposal encourage economic efficiencies?

The proposal will encourage economic efficiencies by focusing on a pro-active instead of a re-active approach typically used in most health care systems currently. IPM will

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remain pro-active and therefore reducing overall health care costs and increasing quality of life outcomes.

c. What information will be made available to the community that will encourage a competitive market for health care services?

Positive outcomes and quality assurance outcomes will be available to the public upon request. For the most part quality outcomes will be used to increase census and to increase quality of care processes.

- 4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
- a. How will this proposal help health care providers adhere to professional standards?

This proposal will assist health care providers to adhere to and follow professional standards by working in collaboration with IPM to drive higher clinical outcomes and patient satisfaction.

b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?

IPM's proposed services will work to continually challenge and encourage active listening and evidence-based practices in regards to the implanted intrathecal pump patient population. Based on knowledge base and experience with the intended population, correlations can be derived and presented to the physicians for review. This will increase the MD knowledge base and therefore drive higher patient outcomes.

- 5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.*
- a. How will this proposal provide employment opportunities for the health care workforce?

This proposal will provide opportunities for skilled Registered Nurses who have shown strong nursing skills and whom wish to be challenged in a high acuity, specialized therapy. In addition, this proposal will serve the existing and new MDs to utilize this treatment modality and offer the option to more individuals whom might benefit.

b. How will this proposal complement the existing Service Area workforce?

The proposal will complement the existing workforce by working alongside the existing HHAs encouraging referrals for services out of IPM's scope and creating a network of providers both MDs and RNs caring for the individuals in the home care setting.

11. Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services, Items 1 through 4)

In the response, the applicant notes its intrathecal home infusion services will be necessary in achieving optimal patient treatment outcomes. What experience does the applicant have with HHA operations in other states in achieving optimal outcomes? Please complete the table below to identify some of the key obstacles the applicant has encountered in other states:

	2012	2013	2014 (YTD)
Total intrathecal home infusion patients			
Number of home patients whose infusion has been delayed			
Number of days of delay in initiation of home infusion services			
Number of additional days in the hospital due to delays in initiation home infusion services			*

Review of the Tennessee Department of Health "Licensed Facilities" report on the Department's website revealed that there are 157 home health agencies (HHA) presently licensed to serve in Tennessee. Because the scope of the project includes the creation of a home health agency, the applicant must include all existing licensed HHAs authorized to serve the statewide service area in order to apply the need formula correctly and identify the net need for any additional agencies at this time and four years in the future (CY2018).

The first step is to complete the table in Exhibit 1 below by identifying all licensed home health agencies, the counties they are licensed to serve, and their most recent utilization as reported to the Department of Health in the Joint Annual Report (JAR). A link to the Department's JAR can be found on the toolbox on the HSDA website. In addition, please note that a listing of all current home health agencies & their licensed service areas is attached to this questionnaire. If you have any questions about the agency listing, please contact Alecia Craighead, HSDA Statistical Analyst at 615-253-2782 to discuss further.

Exhibit 1
Existing Licensed HHAS & Their Utilization serving the 95 County Declared Service Area

Agency Name	County of	Total Counties	2010 JAR	2011 JAR	2012 JAR
(license #)*	Parent	authorized in	Total	Total patients	Total patients
, ,	Office	license	patients	served	served
		(# counties in	served		

	 	 9:26 a	n
	service area) **		
		- Ware	
Total# HHAS 157			

^{*} Please highlight any HHA in bold font that offers intrathecal home infusion services, even if on a limited basis.

The next step regarding the need formula for home health services (Items 2-4) is to collate the data and show your work in the chart in Exhibit 2 that follows:

Exhibit 2
Home Health Need Formula in the Applicant's 95-county Service Area

County (A)	# Authorized Agencies* (B)	2014 Pop* (C)	Patients served (2013) (D)	Use Rate (Patient /1000 pop.) (E)	2018 Pop (F)	Projected Capacity (G)	Projected Need (H)	Additional Need (Surplus) for 2018 (G-H)
Please list all 95 counties Examples are provided for the eastern division of TN below	1 2 00			(Column D Divided by Column C)	- 13.12	Column E Times Column F	Column F Times 0.015	Column G Minus Column H
Anderson	24							
Bedford	25							
Benton	16							
Blount`	19	105						
Bradley	20			a Ini	- 11			
Campbell	24	4		Total Total	1		to the	
Cannon	25							
Carroll	16							
Carter	12							
Cheatham	31							
Chester	15							
Claiborne	23							
Clay	11							
Cocke	19							
Coffee	23							
Crockett	15							
Cumberland	20							
Davidson	37							

^{**} Please show the # of all counties for each HHA. The # of counties in the applicant's service area should be shown separately in the bracket.

				9:26	am	
Decatur	17		E			
DeKalb	29					
Dickson	29					
Dyer	14					
Fayette	30					
Fentress	15					
Franklin	19					
Gibson	17					
Giles	14					
Grainger	22					
Greene	21					
Grundy	26					
Hamblen	21	4				
Hamilton	21	+				
Hancock	20					
Hawkins	22					
Haywood	20	1				
Henderson	13					
Henry	15	1				
Hickman	25					
Houston	16					
	20	-				
Humphreys						
Jackson	15	-				
Jefferson	19	4				
Johnson	11					
Knox	25	-				
Lake	8				74	
Lauderdale	19					
Lawrence	16					
Lewis	16					
Lincoln	16					
Loudon	25					
McMinn	24	4				
McNairy	17					
Macon	23					
Madison	20					
Marion	19					
Marshall	24					
Maury	26					
Meigs	23					
Monroe	21					
Montgomery	25					
Moore	14					
Morgan	25					
Obion	14					
Overton	14					
Perry	14					
Pickett	13					
Polk	17					
Putnam	20					

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				 	9:26	am	
Rhea	22						
Roane	26						
Robertson	31	-					
Rutherford	38						
Scott	21						
Sequatchie	20						
Sevier	18						
Shelby	28	9					
Smith	25		- 8				i
Stewart	12						
Sullivan	15						
Sumner	32						
Tipton	29						
Trousdale	24						
Unicoi	14						
Union	24						
Van Buren	18						
Warren	27						
Washington	16						
Wayne	12						
Weakley	18						
White	21						
Williamson	36						
Wilson	36						
Total							

^{*} The official population source used by HSDA is the TN Dept. of Health, Division of Health Statistics' Population Projections, 2010-2020. This data is available through the applicant's toolbox on the HSDA website.

Please see Attachment C.Need-Item 1.a. for requested information corresponding to Exhibit 1:

Existing Licensed HHAS & Their Utilization serving the 95 County Declared Service Area. Please note that, of all of Tennessee's licensed HHAs, only 2 state that they are able to offer intrathecal services of the home, and only one of these agencies is currently providing such services.

The attached and proposed table in *Exhibit 2* is not applicable to intrathecal homecare services. Unlike traditional infusion services, the typical indicators cannot be used such as number of additional days in the hospital due to delays in initiation home infusion services, or number of days of delay in initiation of home infusion services. This particular therapy is only initiated by a neurosurgeon, or implanting physician, not by a Registered Nurse. The RN can continue and assist with the home management, but the proposed service model will assist only with management.

Two important indicators for this specific type of therapy might be:

 Average number of days pts must wait for MD appointments for required dose changes (7 to 10 business days)

- Average number of days pts must wait for required dose changes with IPM intrathecal home management (1 business day)
- Average number of hospitalizations for pump complications per year utilizing the MD office model (2/year)
- Average number of hospitalizations for pump complications per year utilizing IPM proposed model (0.2/year) (please see Attachment C.Need-Item 1.b.)

12. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

The applicant provided responses to the some of the project-specific standards, including letters of support from representatives of 2 medical equipment vendors. Please answer the questions below about the two vendors:

Medtronics – please describe the nature and scope of business operations by Smokey Mountain Medtronic district. In your response please include location of vendor's main office, counties covered, years in existence, and give brief biographies of the 2 individuals from the vendor that provided the letters of support.

Medtronic is the worlds largest medical technology company, offering a depth of innovative therapies to fulfill their mission of alleviating pain, restoring health, and extending life. Medtronic was founded in 1949, with their world headquarters in Minneapolis, Minnesota. Medtronic has several different divisions, including Neuromodulation, Spine and Surgical Therapies. Medtronic serves 140 countries and is MDT on the NYSE (New York Stock Exchange). The Smokey Mountain Medtronic district has provided IPM with documentation that the proposed services would be beneficial for the individuals in Tennessee whom utilize the Medtronic Implantable Intrathecal Pump. The proposed service model would actually facilitate an increase in pump sales for Medtronic due to the elimination of the MD burden of care for the intrathecal pump. IPM is not affiliated with Medtronic formally, but Medtronic recommend the proposed services.

Flowonix – is this strictly a manufacturer located in New Jersey? Please briefly describe the nature & scope of its business operations in the US and Tennessee.

Flowonix is another manufacturer of a programmable implanted intrathecal pump. Flowonix home headquarters is located in New Jersey, but they do have a national presence with intensity in the state of Tennessee. Flowonix is a medical device company dedicated to helping those who suffer from chronic disorders. Our team has decades of experience developing unique and reliable medical devices to improve patients' quality of life. Using one of a kind technology that delivers industry-leading accuracy, Flowonix has developed an implantable drug pump designed to deliver therapeutic drugs into the spine to relieve a variety of chronic disorders and help patients return to normal lives.

Flowonix is focused on alleviating chronic pain. We are dedicated to working with healthcare professionals to help ease suffering and allow people to reclaim their lives through innovation and therapy advancements.

Letters from physicians, other referral sources such as hospitals and HHAs, and patients should also be provided as requested in the following standards. Please note the following:

- A. The applicant <u>shall</u> provide letters of intent from physicians and other referral sources pertaining to patient referral.
- B. The applicant <u>shall</u> provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.
- C. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

In your response, please be sure that the letters help quantify the "projected number of cases by service category." Please provide the projected number of cases by service category and referral source.

Please indicate the types of patient visits physicians would refer to the proposed home health agency and the projected number of patients and visits by service category to be provided in the initial year of operation.

Referring physicians would refer their patients for IPM to do all pump refills, titrations, MRI checks and changes in status in the homecare setting. Please see two letters from implated pump patients within the state of Tennessee indicating a need for our services (Attachment C. Need-Item 1.c.).

13. Section C. Need, Item 1 (Specific Criteria: Home Health Services- Items 6a and 6b)

Your response is noted.

Items a and b of the question require that the "average <u>cost</u> per visit" and the "average cost per patient based on the projected number of visits per patient" be disclosed. Please provide your charge information for these items (please note that the average charge per patient visit must correspond to what is reflected in the Projected Data Chart for the project).

Average cost per visit: \$100.

• Average cost per patient: \$200.

Please clarify if the applicant intends to fully charge and file claims for intrathecal home infusion services to commercial payors, including managed care organizations. If so, what is the range of charges for this type of services that may be allowed by the commercial payors in Tennessee? What is the range of allowable charges covered by Medicare for Medicare patients who qualify for and receive intrathecal home infusion services?

- Range of charges for this type of services by commercial payors: \$150-250.
- Range of Allowable charges covered by Medicare patients: Zero. Medicare does not cover home infusion services. Medicare recipients in need of home infusion services would require a secondary commercial insurance plan to cover intrathecal home infusion.

Absent any similar facilities in the service area to provide the requested comparison, what is the prevailing charge in Tennessee based on the information you have identified regarding the current # of Medtronic pumps in operation (300 pumps as estimated by the applicant)?

• Each patient is estimated to need approximately 12 visits per year and have an estimated cost of \$200 per visit. With 300 estimated pumps in the state of Tennessee, an expected charge per year would be approximately \$720,000.

14. Section C, Need, Item 3

The question asked the applicant to identify and justify the reasonableness of the proposed service area. The applicant is declaring all 95 counties of TN as its service area based on information provided by Medtronics (approximately 300 Medtronic pump patients in TN).

Please provide a summary of Medtronics operations in TN with description of its services, products and markets, organizational structure, years of operation, affiliations with hospitals, pharmacies, and distribution/service locations (with addresses).

Using the applicant's estimate of 120 patients in Year 1 with primary diagnoses relative to pain or intractable spasticity, please justify the service area by providing a breakout of patients by patient county in the proposed 95 county service area of residence for the first year of the project.

County	No. of Intrathecal Home	% of total patients
	Infusion patients in county	

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County #1	
County #2	
Etc.	
Total	100%

The data required to breakdown the patient need based on county of residence is not available. This information is proprietary to Medtronic and not available to the public. Medtronic provided the number of pts in Tennessee, but no further information will be provided based upon the percentage of pts in each county. As Flowonix is a relatively new player in the implantable intrathecal market, and their pump numbers are continuously increasing within the state of Tennessee, they could not provide an accurate projection to IPM.

15. Section C, Need, Item 4.a.

The applicant states that its services will be provided to patients with clinical conditions ranging from chronic pain to intractable spasticity (such as those suffering from Multiple Sclerosis). In addition, the applicant notes the key benefits of its proposal as follows:

- Majority of population benefits from home infusion
- IPM nurses will manage all aspects of the implanted intrathecal pump in the home
- RN will obtain signed physician orders for all implementation of intrathecal therapy
- IPM acts as extension to physician office to facilitate highest outcomes
- IPM fills, titrates, trouble shoots, supplies meds and manages intrathecal pumps in home setting
- For a variety of reasons, many patients suffer hardships to physically get to physician offices for a pump therapy that can be safely managed at home

In order to understand these benefits more clearly, please also address the following:

- the process licensed pharmacies will follow to prepare and provide medications for the applicant's patients in accordance with physician orders
- how the applicant plans to serve as an "extension to the physician" and the specific responsibilities that would apply such as those that fall under scope of practice and DEA requirements, etc.
- IPM's responsibility for managing infection control, patient & caregiver training; process for equipment safety and maintenance, etc.

Please cite IPM's experience in other states and identify any active licenses. Is the applicant or owner Medicare/Medicaid certified, is it accredited (if so by whom)?

Using current and projected population data from the Department of Health; and the most recent enrollee data from the Bureau of TennCare and demographic information from the US Census Bureau, complete the following table and include data for each county in your proposed service area:

Demographic Variable/Geographic Area	Total Population- Current Year	Total Population- Projected Year	Total Population-% change	*Target Population- Current Year	*Target Population- Projected Year	Target Population-% change	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
County A												
County B, etc.												
Service Area Total												
State of TN Total												

*Target Population is population that project will primarily serve. For example, nursing home, home health agency, hospice agency projects typically primarily serve the Age 65+ population; projects for the discontinuance of OB services would mainly affect Females Age 15-44; projects for child and adolescent psychiatric services will serve the Population Ages 0-19. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from current year, e.g., if Current Year is 2014, then default Projected Year is 2018

Any contracted infusion pharmacy that IPM has chosen to contract with will hold JCAHO Accreditation and follow all state and federal regulations in regards to intrathecal medications and narcotics. The pharmacy will also follow all 797 Pharmacy standards as regulated by pharmacy law. The compounding pharmacy will be supplied the signed MD order via fax. The compounding pharmacy will then process and compound the medication. The compounding pharmacy will then mail the medication with a copy of the signed order to the primary IPM RN. The signed order will be dated and have all of the following:

Patient Name
D.O.B.
Patient Address
Medication
Concentration
Medication Daily Dose
Volume to be filled

IPM and their RN employees will serve as an "extension to the physician" by implementing strong clinical and assessment skills based on MD orders. The IPM RN will not work out of his/her scope and the Tennessee Nurse Practice Act as stated in the Tennessee Regulatory Statutes. The IPM RN will perform the following: a full nursing assessment, education, and clinical expertise in the intrathecal pump based on signed MD orders. This structure allows the prescribing MD a glimpse of the patient in his or her own environment. Also allowing the RN to witness and identify any changes in

ambulation, family dynamics and or unsafe conditions that can all lead the patient to below optimal outcomes. The extension of the RN in the home allows the MD to be aware of findings that could not be witnessed or identified in the MD office setting. This approach increases MD awareness of patient needs and services required to obtain optimal outcomes.

Please see attached IPM Quality Assurance Program (Attachment C. Need-Item 4.a.1.), Policy for Equipment Management (Attachment C. Need-Item 4.a.2.), and Policy for Patient/Caregiver Education (Attachment C. Need-Item 4.a.3.) that address IPM's responsibility for managing infection control, patient and caregiver training, and process for equipment safety and maintenance.

IPM is a relatively new company and is actively seeing pts in New Jersey, and just recently JCAHO accredited in the state of Florida. IPM is not Medicare/Medicaid Certified and will not proceed to do so.

Regarding the use of current and projected data in order to complete the attached demographics chart, this question cannot be answered simply because the data is not available from manufacturers as to the county breakdown of individuals with implanted programmable pumps.

16. Section C, Need, Item 4.B

What percentage of total patients is the applicant forecasting that will be medically indigent in Year 1 and Year 2 of the project?

Zero percent, IPM will work with individuals only with insurance coverage with home care benefits available.

17. Section C, Need, Item 5

The applicant maintains that "historically, intrathecal therapy has been riddled with errors and negative results and that the IPM model will have higher therapy success rates due to quality, education, knowledge and overall proactive approach". Please discuss in more detail by giving specific examples of types of errors and the applicant's efforts to achieve positive results.

The applicant must address the utilization of all existing home health agencies in its proposed service area. Generally speaking, the metrics provided for this question should be very similar to the utilization information you were asked to provide for HHAs in the responses to the questions pertaining to the project specific criteria for home health services.

With the type of therapy proposed, the historical data has shown that human error is the most common error in this therapy. IPM has taken several steps to reduce and or eliminate the risk for error with this type of therapy. Based on the medication being delivered directly into the spinal column (intrathecal space) this therapy must be exact. IPM's theory is as follows: "there is no room for error". The potential errors with this therapy can be as follows:

- Incorrect programming
- Incorrect medication
- Missing alarm dates
- Potential pocket fills
- Not recognizing potential red flags of the therapy.

IPM starts by training the RN's based on the manufacturer training. Each RN is not only trained on the actual programmer and pump refill, but also with theory, mechanics and problem solving. This approach allows the RN to fully understand they mechanical system, components, programming, and limitations of the entire system (catheter and pump), not only the refill and programming portion. The IPM RN also has the luxury of having this therapy be his/her sole focus. This theory is very important because in the field of nursing, as with many other fields, the more you practice and immerse yourself in the skill, or field, the better and stronger one becomes. The sole focus philosophy is really what will set IPM apart from many of the existing 157 licensed HHA's in the state of Tennessee. Although a few other agencies do the therapy (1 out of 157), only IPM focuses solely on intrathecal home management. This will allow IPM to be the premier provider in safety and clinical skill for the proposed services. IPM has taken extensive steps from triple checking medications, to extensive sole focus nursing staff to greatly reduce and or eliminate errors.

IPM utilized the existing list of licensed HHA's provided by the state of Tennessee, only two licensed HHAs admitted to performing intrathecal home care management with a response, "Yes, but it depends on a lot of things, severity, insurance". Given this documentation (see attached HHA Utilization Chart) the results encourage the need for a qualified, licensed HHA with a sole focus on intrathecal home management to begin services.

18. Section C, Need, Item 6 and Section C, Economic Feasibility, Item 4 (Projected Data Chart)

The methodology of projecting 120 patients in Year One is noted. However, please also describe the method used to estimate the other variables needed to project gross annual operating revenue, such as (a) identification of the types and estimated quantities of infusion products for its patients such as pain management medications, (b) the average # of visits per patient per year, and (c) the average gross charge per visit. In your response, please summarize all calculations and assumptions such as the

9:26 am number of physician referrals needed to admit 120 patients in the first year of the project.

(a) Identification of the types and estimated quantities of infusion products for its patients such as pain management medications:
Infusion products such as medication will not be a variable effecting gross annual operating revenue because the contracted pharmacy will bill for these products directly.

(b) The average number of visits per patient per year: Estimated to be approximately 12 visits per year.

(c) The average gross charge per visit: \$ 200 per visit.

Each patient admission will need its own referral. Therefore, 120 patients will require 120 referrals.

In addition, please provide documentation from physicians from each of the three Grand Divisions of Tennessee (East, Middle and West) that attests to their interest and ability to refer patients to the proposed intrathecal home therapy services program.

IPM is expecting that all referrals will come from Medtronic and Flowonix representatives directly and the requested documentation (letters to attest interest and ability) have previously been submitted with the initial application.

Please briefly describe a typical visit – include length of time, standard services covered, frequency of visits with physician, how refill orders are processed, and how other services that may be needed will be provided (e.g. homemaker aide assistance).

A typical visit from an IPM RN would be about 60 minutes but may be up to 2 hours in duration. Some visits will exceed 60 minutes, for example an admission visit will be closer to 120 minutes in duration. The typical visit consists of the following components: introduction, full nursing assessment, education, pump interrogation, refill and or titration ordered by MD, end assessment with vital signs and lastly confirmation of the next scheduled visit with review of the telemetry from the encounter. Each physician will determine the frequency of visits required in his/her office. The normal is anywhere from 1 to four times per year, based on severity of disease process, exacerbations, and other compounding factors. Refill orders are processed by IPM and send to the contracted pharmacy for compounding and delivery. IPM tracks all alarm dates, next refill visits and any other patient encounters is a computerized patient record system.

The salaries do not reflect the cost of a director of nursing (referenced on page 28), nor do they appear to include sufficient staff to cover 95 counties, an administrator of the HHA or 24-hour on call staff. Please explain.

Primary RN Salary: \$70,000

- The Primary RN is responsible for DON, administrator and 24 hour on call responsibilities. (The initial application included the contracted services of a 24hour call center. At his point, IPM has decided to amend this original proposal and utilize the DON/Administrator with 9 years of experience in this therapy as the 24-hour emergency and on call contact for patients, physicians and nurses.)
- Secondary RN Salary: \$55,000.
- Tertiary RN (per-diem) reimbursement rate: \$100/per visit (number of visits would depend on number of cases which would not be able to be predicted at this time).

Please identify the number of visits by primary type of service category for each year.

The primary type of intrathecal pump home visits service category is the only type of service category that will be provided by IPM. IPM is estimating that approximately 12 visits a year to be done on each patient.

Please explain why the projected supply cost decreases from Year 1 to Year 2 despite an increase in patients and staffing.

The projected supply costs decrease from Year 1 to Year 2 to account for the initial "startup" supplies that may be needed (i.e. desk, computer, phone, etc).

19. Section C. Economic Feasibility Item 1 (Project Cost Chart)

Your response is noted. In accordance with the application instructions on page 14 of the HSDA application template, please confirm that the cost of the office space in line B.1 of the chart is based on the higher of the rental cost over the term of the rental agreement or the fair market value cost of the office space. The higher of the 2 amounts must be used for this chart.

There is a math error with line D of the chart. Please clarify and provide a revised chart.

Please refer to an amended Project Cost Chart within our resubmitted application, which reflects the additional expense of our rental agreement addendum.

20. Section C, Economic Feasibility, Item 3

The applicant notes benefits of the proposal that include access to unique service, improved health outcomes and earlier detection of secondary infections. Please describe the types of patient outcomes and give examples of the applicant's track record of these in other states. In discussing favorable outcomes with detection or management of secondary infections, please describe specific cases referenced. Does IPM plan to provide this care or refer to other HHAs?

IPM can increase optimal patient outcomes by using their pro-active approach with the physician and the patient. IPM will assist in the reduction of secondary infections such as: urinary tract infections, changes in skin integrity, and respiratory exacerbations. The early detection of the before mentioned secondary issues is critical in achieving the best outcomes for the patients. Although IPM does not do wound care, or IV infusions, or any other service not related to intrathecal homecare management, IPM plans to establish a network with the existing licensed HHA's for patient needs and skilled services. Early intervention in every case offers the best overall results. The higher patient outcomes will also lead to an increase in workforce for the applicable patients, a higher patient quality of life, and in many times better overall health outcomes.

21. Section C. Economic Feasibility Item 6. B

The all-inclusive charge of \$200 per patient visit is noted. Does the charge also include the cost of the medication? Please clarify.

This is incorrect: the \$200 charge is reimbursement for the nursing visit only. This charge does not include cost of the medication because all medication will be billed directly by the contracted pharmacy compounding it.

Please provide a comparison to allowable charges covered by commercial/managed care 3rd parties and Medicare.

Unfortunately, there is not a comparison to be made because Medicare does not cover in home nursing visits related to intrathecal therapies.

22. Section C, Economic Feasibility, Item 7

As noted previously, the projected staffing of one registered nurse in Year 1 of the project (2015), does not appear to meet HHA licensing requirements. Please reestimate the staffing needed and revise the salary cost in a revised Projected Data Chart.

Our revised salary cost is as follows: \$125,000 + any per diem RN charges that would not be predictable at this point in time.

• Primary RN: \$70,000

Secondary RN: \$55,000

Tertiary RN: \$100/per visit

IPM is planning to begin nursing services utilizing a DON, one full time RN, and per diem nursing coverage as needed depending on the number of cases. As IPM patient census reaches approximately 75 cases, IPM will expect the need for a tertiary full time RN.

23. Section C, Economic Feasibility, Item 9

Please complete the following chart for the proposed HHA.

Payor	Year One Gross	% of Total
	Revenues	Revenues
Medicare	\$0	0%
Medicaid/TennCare	\$0	0%
Commercial insurance	\$137,758.50	99%
Self-Pay	\$1,391.50	1%
Charity	\$0	0%
Total	\$139,150.00	100%

Please note the above completed chart, reflecting a breakdown of anticipated revenue sources for our first year of operation.

24. Section C, Economic Feasibility, Item 10

The copies of the owner's checking account statement are noted. Since the project is financed from cash reserves, please also provide a balance sheet and income statement.

Please refer to the enclosed requested balance sheet (Attachment C. Economic-Item 10.a.) and income statement (Attachment C. Economic-Item 10.b.), as well as an updated checking account statement dated June 30th, 2014 (Attachment C. Economic-Item 10.c.).

25. Section C, Contribution to Orderly Development, Items 1 and 2

The response is noted. Given the nature of the clinical services, please clarify why there is an absence of any professional service arrangements, emergency transfer agreements, etc. Please explain how this contributes to the orderly development of health care.

The need for arrangements with emergency transfer and or any other professional services is not required with the proposed service model. The individual will continue to use the transfer services that they utilized prior to IPM services. IPM has a sole focus, so a change in transportation is not required.

In the second item, the applicant states that medical professionals specializing in either pain management or neurology will work with the proposed IPM services. In addition, the applicant comments that the introduction of its intrathecal home infusion program will allow these professionals the option of expanding their treatment modality. Please explain how the geographic aspects of referral

coordination would not be an important consideration. For example, please identify the reasons that a pain management physician in Memphis would want to refer patients to a home health agency in Knoxville in lieu of continuing to provide care in his/her medical office. Please clarify.

Due to the vast area that IPM will be able to service the geographic area of a physician referral will be up to 180 miles of the physician's office. This seems extreme in the common patient and physician relationship, but due to the extension of services that IPM provides, physicians could safely and closely monitor their patients' while only seeing them one to four times a year. The IPM service model allows physicians to increase their "catchment" area and service individuals whom might not have access to quality pain and or spasticity care. It is important to remember that the physicians that work with intrathecal pumps are highly specialized in their field and are not generally as numerous in numbers as general practitioners.

The applicant notes that IPM's use of a whole patient approach is indicative of a patient management approach that can lead to reduction of ER visits by over 50%. Please briefly describe the source of this outcome and provide a copy of the survey or study that documents the reduction in ED visits.

A competing company has utilized the intrathecal homecare model in New Jersey for over 19 years and the results are indicated in the attached graph, mentioned in a previous response (see Attachment C. Need-Item 1.b.).

Please describe how the applicant's plans to not participate in Medicare and TennCare contributes to orderly development in Tennessee.

IPM is only able to work with individuals whom have insurance coverage that allows a homecare benefit. Even though this does exclude some individuals, the benefit of those that can be assisted is great and should be available to Tennesseans.

As noted for the project specific criteria, please provide letters of recommendation or similar testimonials that attest to this level of support.

Please refer to aforementioned letters from implanted pump patients within Tennessee indicating an immediate need for our services (Attachment C. Need-Item 1.c.), supplemental to the three letters submitted with our original application.

26. Section C, Contribution to Orderly Development, Item 4

It is unclear how this question pertaining to the availability and accessibility to professional staff would not be applicable to the proposed home health agency. It would be helpful to identify the type of training and certification requirements that registered nurses must complete to provide intrathecal home infusion services. In

addition, please briefly summarize the staffing requirements that apply to home health agencies as a condition of licensing by the Tennessee Department of Health and how the applicant intends to comply with same.

The availability and accessibility to professional staff is important to IPM, although the qualifications to work at IPM are very rigorous. It is highly uncommon to find a RN that has experience in this niche therapy. Therefore, IPM recruits and then performs a rigorous three to six month training specializing in intrathecal home management.

IPM intends to comply with all Tennessee statutes stated in the licensing of a home health agency. IPM will do this by hiring licensed personnel with the required education and experience to fill each position as stated in Tennessee statutes.

In other recent home health infusion therapy projects, plans were discussed to recruit a pool of Certified Infusion Registered Nurses (CIRN) to serve patients in their service area. In addition, one applicant envisioned using between 8 and 15 per diem Certified Infusion Registered Nurses (CIRN) to staff a 38 county proposed service area. Are there any circumstances the applicant can identify that may warrant using per diem certified infusion therapy RNs to provide patient care in all counties of Tennessee? Please discuss.

Per Diem RN's may be considered for over flow of patients, but only if the (CIRN) Certified Infusion Registered Nurse is also trained and proficient in intrathecal therapy. The national accrediting board for infusion nurses does not include intrathecal home infusion as a topic and training for the accreditation. Although a CIRN would be beneficial to IPM, they would still have to go through all of the 3 to 6 month training for safety of the patient and for a full understanding of the therapy.

27. Section C, Contribution to Orderly Development, Item 7.a.

The response is noted. What accreditation for home health agencies applies to this service? In your response, please clarify why the applicant would not seek same for the proposed home health agency.

IPM does have plans to become The Joint Commission Accredited for home care nursing. IPM is currently JCAHO Accredited in the state of Florida and will plan also in the state of Tennessee. JCAHO Accreditation will assist IPM in maintaining high standards and protocols.

Home Health Agencies are required to have a process in place to assess and manage patient pain. In addition, agency regulations require physician supervision of patient care, including the plan of care (POC) developed for each patient and review by the MD at least once every 62 days or more often if severity of the patient's condition

9:26 am requires. Please describe how the applicant intends to comply with these patient care requirements as a condition of licensure in Tennessee.

Please refer to the attached Policy and Procedure for IPM (see Attachment C. Contribution-Item 7.a.).

Please describe the minimal staffing requirements that apply to licensed home health agencies in Tennessee and describe how the applicant intends to comply with same.

A home health agency must have an administrator whom is readily available for the staff and administrative functions and also a RN that is cross trained and can stand in for the administrator if necessary or exceeding fifteen days. IPM will successfully maintain and function within the set statutes and rules of Tennessee State Home Health Regulations as described within our aforementioned Policies and Procedures.

28. Proof of Publication

The copies of the Letter of Intent in 18 newspapers of general circulation appear to cover 94 of 95 Tennessee counties, the exception being Hardin County. Notification in the Commercial Appeal, Jackson Sun and the Buffalo River Review (all publications of general circulation) is noted for counties that border Hardin County, including Wayne, Decatur, Chester and McNairy Counties; however no mention of Hardin County could be identified. Please clarify the status of same for Hardin County.

As confirmed by a Senior Media Buyer at the press service that we utilized for our Publication of Intent, Hardin County is covered by both the Memphis Commercial Appeal and the Jackson Sun (from Madison County).

In your response, please also provide proof of publication that documents publication of the applicant's Letter of Intent (LOI) in all the newspapers that apply (names of the 18 newspapers are included in table below). It is important to note that the requested proof of publication must be in the form of either a copy of the full page of the newspaper in which the applicant's LOI appeared with the mast and dateline intact or an affidavit from the newspaper's publisher that attests to the date the applicant's LOI was published and the counties included in the newspapers coverage area/area of general circulation. Please insure the correct complete copy is paired with each appropriate affidavit.

Newspaper	# TN Counties Included in Newspapers Coverage Area (as noted in copies of LOIs submitted to HSDA)
Tennessean	29
Commercial Appeal	14 - 15

	5.20 am
Paris Post Intelligencer	4
Daily News Journal	7
McMinnville general Standard	4
Buffalo River Review	3
Knoxville News Sentinel	17
Murfreesboro Daily News	5
Johnson City Press	7
Kingsport Times	6
Jackson Sun	5 6
Greenville Sun	3
Clarksville The Leaf Chronicle	1
Cookeville Herald Tribune	7
Dyersburg State Gazette	5
Chattanooga Free Times Press	16
Rogersville review	6
Bristol Herald Courier	6

Please note that we have amended the above table to reflect the coverage of Hardin-County by the Commercial Appeal and the Jackson Sun.

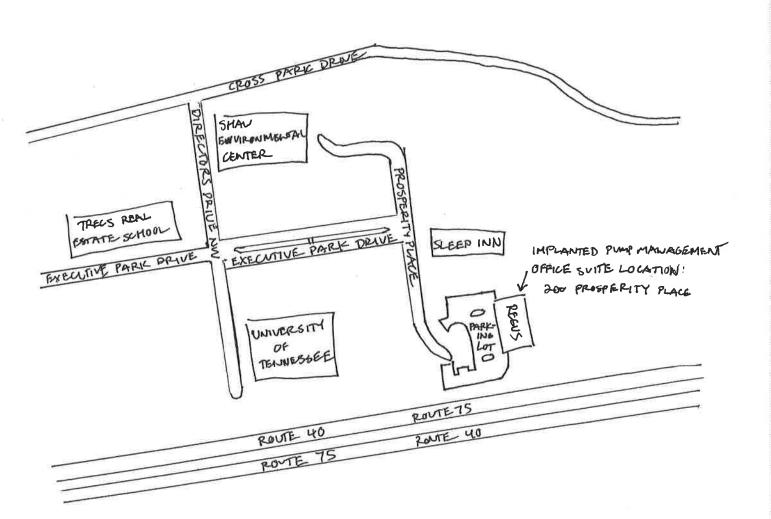
Enclosed is a signed affidavit attesting to the publication coverage as stated within our Letter of Intent (see Attachment 28-Publication).

124

SUPPLEMENTAL #1

July 28, 2014 9:26 am

Attachment B.3...



TOTAL ACREAGE = 1.91

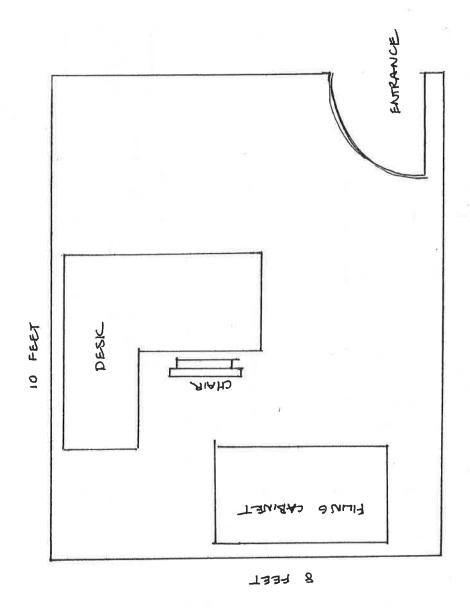
126

SUPPLEMENTAL #1

July 28, 2014 9:26 am

Attachment B.4.

HALLWAY



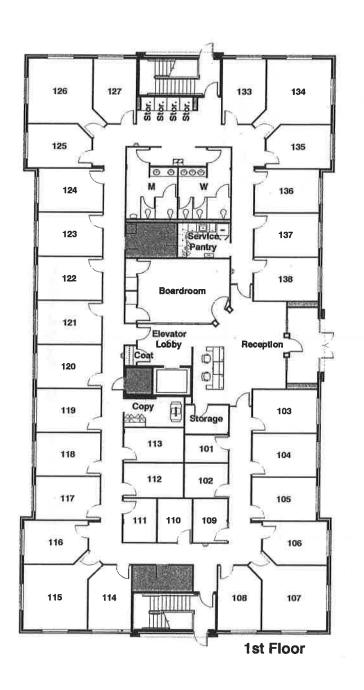
#102

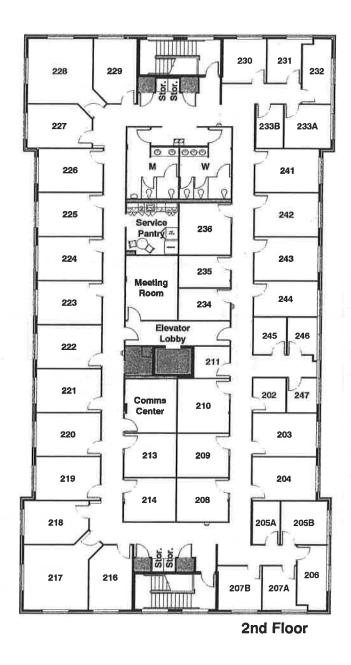
OFFICE

FLOOP PLAN -

エトレミス

TOTAL AREA: 80 SOUARE FEET





129

SUPPLEMENTAL #1

July 28, 2014 9:26 am

Attachment C.Need-Item 1.a.

Agency	Address	Phone Number	Fax Number/Other	Intrathecal home infusion?	# Counties serviced	Health Agency Location
Clinch River Home Health	Clinch River Home Health 401 Sulphur Springs Road, Clinton, TN, 37716	Phone: 865-457- 4263 Phone 2: 865-687- 7070	Fax: 865-457-9415 Fax: 865-687-7040 office@crhh.net	ON		
Home Option by Harden Health Care, The	800 Oak Ridge Turnpike, Suite A208, Oak Ridge, Tennessee 37830	Phone: 865-220- 1700	N/A	ON		
Professional Case Management of Tennessee	800 Oak Ridge Turnpike #100, Oak Ridge, TN 37830	Phone:(865) 481- 4800	N/A	IV Infusion Therapy Only		
Blount Memorial Hospital Home Health Services	1095 East Lamar Alexander Parkway, Maryville, TN 37804	Phone:865-981- 2160	N/A	IV Infusion Therapy Only		
Elk Valley Health Services Inc	5249 Harding Place Nashville, TN 37217	Phone: (615) 360- 1116	Fax: (615) 360-7895	ON		
Quality Home Health		Phone:(865) 531- 0016	Fax: (865) 470-2194	ON		
Amedisys Home Health Care	120 S. Main St. Pikeville, Tennessee 37367	423-447-6841	423-267-9839	NO (IV Only)		
Premier Support Services, Inc	1835 BUFFALO TRAIL MORRISTOWN, TN 37814	Phone: (423) 587- 8771		ON		
Univ. of TN Med. Ctr Home Health/Hospice Service	1924 Alcoa Highway, Knoxville, Tennessee 37920	Phone: (865) 305- 9000		ON		
Amedisys Home Health	5959 S. Sherwood Forest Bivd. Baton Rouge, LA 70816	tel. (225) 292-2031		ON		
Amedisys Home Health Care	230 Cumberland Bend, Suite D, Nashville, TN 37228	Phone: (615) 313- 7400	Fax: (615) 313-7410	ON		
Camellia Home Health of East Tennessee				Yes	A lot (wouldn't	
	1700 Liberty St NW, Knoxville, TN 37921	(865) 584-4010			list)	Knoxville
Covenant nomecare	3001 Lake Brook Blvd., Surte 101, Knoxville, IN 3/909	(865) 374-0600		ON		
East Tennessee Children's Hospital Home Health	2018 W Clinch Ave, Knoxville, TN 37916	865-541-8000		ON :		
Gentiva Health Services 7 (Girling Health Care)	02.25 rigniand P1 Way, Knoxville, IN 37919	(865) 584-3133		NO	,	
Maxim Healthcare Services. Inc	7417 Kingston Dike #102 Knowille TN 37919	865 330 3336		Q.		
NHC Homecare	9000 Executive Park Dr A205. Knoxville. 37923	(865) 539-0242				
Tennova Home Health	10820 Parkside Drive, knoxville, TN. 37934	(865) 218-7011	3.5	No (Does Home Infusion)		
UTMCK-Home Care Services: Hospice & Home Care	1924 Alcoa Highway, Knoxville, Tennessee 37920	(865) 305-9000		No		
Intrepid USA Healthcare Services	114 S David Lane Unit 11 Parkway Plaza, Knoxville, TN 37922	865-531-1415	865-539-8047	YES (Not many depends on a lot of things) (insurance, severity)	55	Texas 6
Professional Home Health Care Agency	2221 Jacksboro Pike, La Follette, TN, 37766	(423) 562-6870 (disconnected)				:26
ANDERSON COUNTY						ar
Heritage Home Healh	635 N. Main St., Suite D. Shelbwille, TN 37160	931-684-2118	931-685-5355	CN		n
Suncrest Home Health	1914 Mcarthur Street, Manchester, TN 37355	(931) 728-2453	000	NO (DO HOME INFUSION)		
Alere Women's and Children's Health, LLC	651 E 4th St Ste 100, Chattanooga, TN 37403-1923	(901) 767-8802		ON		
Angel Private Duty and Home Health, Inc.	333 PLUS PARK BLVD, NASHVILLE, TN 37217-1005	(615) 365-4424	(615) 365-0998	ON		
Careall	4015 Travis Dr #200, Nashville, TN 37211	(615) 835-4445		ON		
Coram CVS Specialty Infusion Services	1828 Midpark Drive, Suite D, Knoxville, TN, 37921-5900	865-450-2380	865.450.2385	ON		
rijendsnip nome neatri Agency	555 PLUS PARK BLVD, NASRVIIIE, IN 3/21/	(615)-365-4424	(615) 365-0998	ON		

Willowbrook Home Health Care Agency 2006 Coven Highway, Winchester, IN 37128 Deaconest Medical Charles of Winchester, LLC 2006 Coven Highway, Winchester, IN 37348 Deaconest Nemecrae Lincoln Medical Home Health & Hospice 1797 Wilson Pkwy, Fayetteville, TN 37344 Lincoln Medical Home Health & Hospice 1797 Wilson Pkwy, Fayetteville, TN 37344 Lincoln Medical Home Health of Mashville, Inc. 1896 General George Patton Stor, Franklin, TN 37057 BEDFOND COLUNTY Tennessee Quality Homecare - Northwest 500 Wilson Run, Brentwood, TN 37227 Baptist Memorial Home Care & Hospice 550 Vilson Run, Brentwood, TN 38320 Tennessee Quality Homecare - Southwest 500 Vilson Run, Brentwood, TN 38320 Tennessee Quality Homecare - Southwest 500 Tennessee Ave. North, Parsons, TN 38363 Tennessee Quality Homecare - Southwest 500 Tennessee Ave. North, Parsons, TN 38363 Tennessee Quality Homecare - Lexington 1 125 Boswell St. Lexington, TN 383024 Regional Home Care - Lexington 1 West Tennessee 90 DIRECTORS ROW, Jackson, TN 38305 BEXTON COUNTY Regional Home Care - Jackson 37 Sandstone Circle, Jackson, TN 38305 BERNTON COUNTY Home Health Care of East Tennessee, Inc Continueare Healthservices, Inc I 1501 Riverside Drive, Suite 36, Chattanooga, TN 37406 Life Care at Home of Tennessee Inc Continueare Healthservices, Inc I 1501 Riverside Drive, Suite 36, Chattanooga, TN 37406 Life Care at Home of Tennessee 175 Seorgetown Rd. NW, Cleveland, Tennessee 37312 BLEDSOC COUNTY Family Home Care - Cleveland 175 224h St NW, Cleveland, Tennessee 37312 BLEDSOC COUNTY Family Home Care - Lecweland 175 224h St NW, Cleveland, Tonessee 37312 BLEDSOC COUNTY Family Home Care - Lecweland 175 224h St NW, Cleveland, TN 37312	(615) 382-2044 931-967-0633 (931) 433-2516 (931) 433-8088 (615) 591-8089 (615) 726-0776 731-584-2700 1-800-628-0191 901-227-9000 -org 731-847-9228 1-800-899-2884 (731) 288-6011 Phone: 731-968-1860 Phone: 731-968-1860 1-300	info.womens@bmhcc .org		
2068 Cowan Highway, 1820 Huntsville Hwy, Fay 1896 General George I S00 Wilson Run, Brent S00 Wilson Run, Brent S00 Wilson Run, Brent S25 Humphreys Blvd S80 Tennessee Ave. N S80 Tennessee Ave. N S80 Tennessee Ave. N S90 Tyson Ave., Paris, 2000 Church Street, N 90 DIRECTORS Row, 33 Directors Row Jack S740 Uptain Road, Su 5725 Hamilton Park C 5740 Uptain Road, Su 5755 Georgetown Rd 3775 Georgetown Rd 3775 Georgetown Rd S755 Keith St NW, Clev 3555 Keith St NW, Clev 3550 Keith St NW, Clev 3550 Keith St NW, Clev 3550 Keith St NW, Clev 350 Keith St NW, Clev 350 Keith St NW,	-24			
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1875 U.S. 51, Dyersbu 185 Boswell St. Lexing 301 Tyson Ave., Paris, 2000 Church Street, N 2000 Church Street, N 30 DIRECTORS ROW, 33 Directors Row Jack 37 Sandstone Circle, J 5740 Uptain Road, Su 1501 Riverside Drive, 1 1501 Riverside Drive, 1 1752 Hamilton Park C 3775 Georgetown Rd 1775 Ath St NW, Clev 3555 Ketth St NW, Clev	288-6011 731-968-1860 e: (731) 642-		Intrathecal on site) NO	
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33 Directors Row Jack 37 Sandstone Circle, J 5740 Uptain Road, Su 1501 Riverside Drive, 7625 Hamilton Park C 3775 Georgetown Rd 175 24th St NW, Clev 3555 Keith St NW, Clev	58-1372	(731) 664-9919	NO (IV Only)	
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nessee, Inc 15140 Uptain Road, Su 151 1501 Riverside Drive, 1525 Hamilton Park Dee 1755 Georgetown Rd 175 24th St NW, Clev	7143	FAX 731-668-7677	NO	
5740 Uptain Road, Su 1501 Riverside Drive, 7625 Hamilton Park E 3775 Georgetown Rd 175 24th St NW, Clev 3555 Keith St NW, Clev				
	423.510.9010		NO (IV Only)	
	423-386-1000			
	-815-	info@continucareheal thservices.com	No (IV Only)	
	(423) 510-1500 (423)	(423) 510-1560	NO (IV Only)	
- Cleveland nre, LLC	423-475-2461 423-	423-472-9457	NO (IV Only)	
	(423) 559-6092		(IV)	9:
	423-473-8886		NO (IV)	20
BKADLEY COUNTY				i ai
Home Health Care of Middle Tennessee Two International Drive Suite 901 Nashville, Tn 37217	615.361.4859 615.3	615.361.5187	NO (TEACH ONLY)	m
CANNON COUNTY				
Procare Home Health Services 9 Worth Cir, Johnson City, TN 37601	(423) 434-5130			
	(423) 727-3250		NO(IV)	
Medical Center Homecare - Kingsport 2020 Brookside Dr, Kingsport, TN 37660	(423) 392-3510		ON	
CARTER COUNTY				

Vanderblit Home Care Services CHEATHAM COUNTY CHEATHAM COUNTY CHEATHAM COUNTY CHEATHAM COUNTY Tennessee Quality Homecare - Southwest Tennessee Quality Home Health Green - Southwest Tennessee Quality Homecare - Southwest Tennessee Quality Homecare - Southwest Tennessee Quality Home Health Green - Southwest Tennessee Quality Homecare - South Homecare - South Homecare - Tennessee Guality Home Health Green - Southwest Tennessee Children's Hospital Home Health Tennessee Quality Homecare - Tennessee Guality Home Health Tennessee Children's Hospital Home Health Tennessee Quality Home Health Tennessee Children's Hospital Home Health Tennessee Quality Homecare - Tennessee Guality Home Health Tennessee Quality Homecare - Tennessee Guality Home Health Tennessee Quality Homecare - Tennessee Guality Home Health Tennessee Quality Folion's Hospital Home Health Tennessee Quality Folion's Hospital Home Health	(615) 936-0336 344 (731) 986-3220 ssee 37129 931-796-7149 1-866-385-6423 931-722-6832 (423) 569-8441 (423) 569-4043 (731) 926-8202 Phone 731-968-1860 FAX 731-968-1875 423-447-6841 731-779-3103 731-779-3104 731-422-1100 731-422-4371 Phone 731-668-7143 (888) 401- CARE(2273)	615-384-1438 (423) 569-4043 (423-267-9839 731-779-3104	NO IV Infusion Therapy Only IV Infusion Therapy Only Antibiotic, hydration, TPN (Didn't specify IV vs Intrathecal on site) IV Infusion Therapy Only IV Infusion Therapy Only NO IV Infusion Therapy Only	
813 R B Wilson Drive, 242 Heritage Park Dr. 242 Heritage Park Dr. 28 East Main Street, B 313 S Main St, Wayn 313 S Wayne Rd Ste C, 935 Wayne Rd Ste C, 936 Wayne Rd Ste C, 937 Sandstone Circle, J 937 Sandstone Circle, J 937 Sandstone Circle, J 938 West Main Street Por 939 Cumberland Bend 1151 Tammbell Street 130 Cumberland Bend 1316 East College Str 1246 Main Street Po 940 1700 Liberty St, Knox 1615 West Morris Bo 1122 West Morris Bo	ssee 37129	615-384-1438 (423) 569-4043 (423) 569-4043 (423-267-9839 731-779-3104	NO IV Infusion Therapy Only IV Infusion Therapy Only Antibiotic, hydration, TPN (Didn't specify IV vs Intrathecal on site) IV Infusion Therapy Only IV Infusion Therapy Only NO IV Infusion Therapy Only	
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Services Services Services Services Services Services Services Services		615-384-1438 (423) 569-4043 (423) 569-4043) FAX 731-968-1875 423-267-9839 731-779-3104	IV Infusion Therapy Only Antibiotic, hydration, TPN (Didn't specify IV vs Intrathecal on site) IV Infusion Therapy Only IV Infusion Therapy Only NO NO IV Infusion Therapy Only NO	
Services Services Services Services Services Services Services Services		615-384-1438 (423) 569-4043 (423) 569-4043) FAX 731-968-1875 423-267-9839 731-779-3104	Antibiotic, hydration, TPN (Didn't specify IV vs Intrathecal on site) IV Infusion Therapy Only IV Infusion Therapy Only NO NO IV Infusion Therapy Only	
Services Services Services E Agency E Health Services		615-384-1438 (423) 569-4043)FAX 731-968-1875 423-267-9839 731-779-3104	IV Infusion Therapy Only IV Infusion Therapy Only NO NO IV Infusion Therapy Only	
Services Services E Agency E Agency E Agency E Agency E Agency E Agency E E Health E E E E E E E E E E E E E E E E E E E		(423) 569-4043) FAX 731-968-1875 423-267-9839 731-779-3104 731-422-4371	IV Infusion Therapy Only NO NO IV Infusion Therapy Only NO	
Services Services E Agency B Agency B Agency B B B B B B B B B B B B B B B B B B B	(731) 926-8202 Phone 731-968-1860 423-447-6841 731-779-3103 731-422-1100 Phone 731-668-7143 (888) 401- CARE(2273)) FAX 731-968-1875 423-267-9839 731-779-3104 731-422-4371	NO NO IV Infusion Therapy Only IV Infusion Therapy Only IV Infusion Therapy Only NO	
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Services Services e Regency e Health e Health	423-447-6841 731-779-3103 731-422-1100 Phone 731-668-7143 (888) 401- CARE(2273)	423-267-9839 731-779-3104 731-422-4371	IV Infusion Therapy Only IV Infusion Therapy Only IV Infusion Therapy Only NO	
Services : : : : : : : : : : : : : : : : : : :	731-779-3103 731-422-1100 Phone 731-668-7143 (888) 401- CARE(2273)	731-779-3104 731-422-4371	IV Infusion Therapy Only IV Infusion Therapy Only NO	
Services e Agency e Health	731-422-1100 Phone 731-668-7143 (888) 401- CARE(2273)	731-422-4371	IV Infusion Therapy Only NO	
Services e.e. Agency e. Health e. Health	Phone 731-668-7143 (888) 401- CARE(2273)		ON	
Services e Agency e Health	(888) 401- CARE(2273)	FAX 731-668-7677		
Services e.e. e.e. e.e. Health			IV Infusion Therapy Only	
	423-559-6092	423-559-6093	IV Infusion Therapy Only	
	423-784-2452	423-784-1120	IV Infusion Therapy Only	
	28 615-313-7400		IV Infusion Therapy Only	
	Tel: 731-772-2655	Fax: 731-772-2695	IV Infusion Therapy Only	
	7	423-623-8311	IV Infusion Therapy Only	
			IV Infusion Therapy Only	
	813 (423) 492-8100		ON	
	Phone: (865) 545-		NO Wateroot Thorsely	
	3500			
				9:2
	931-243-3680	800-382-3341	IV Infusion Therapy Only	26
	(615) 598-9662		IV Infusion Therapy Only	а
Coram CVS Specialty Infusion Services 2970 Sidco Drive, Nashville, TN 37204-3715	615.445.3098		2	ım
Highland Rim Home Health Agency 337 N. Cedar Ave. Cookeville Tennessee 38501	931-528-5578		2	
Clay County Total Licensed Agencies				
Advanced Home Care Inc. 1012 Chalidas & Greeneville, TN 27742	0023 001 011		24	
2	423.703.0300	CC2C 2C2	≥ ≥	
gencies	453-787-2000	425-030-2033	2	

SUPPLEMENTAL #1

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Angel Private Duty and Home Health, Inc.	333 PLUS PARK BLVD, NASHVILLE, TN 37217-1005	Phone (615) 365- 442	ON	
Vanderbilt Community & Home Services	1211 Medical Center Drive, Nashville, TN 37232	(615) 322-5000	NO (IV ONLY)	
Caresouth HHA Holdings of Winchester, LLC	2068 Cowan Highway, Winchester, TN 37398	(866) 291-3017	ON	
Lincoln Medical Home Health & Hospice	1797 Wilson Pkwy Fayetteville, TN 37334	(931) 433-8088	IV?	
Friendship Home Health, Inc.	333 Plue Park Blvd, Nashville, TN 37217	(615) 365-4313	ON	
Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	500 Wilson Pike Cir, Brentwood, TN 37027	(615) 726-0776	NO IV ONLY	
Coffee County Total Licensed Agencies				
Baptist Home Care & Hospice - Covington	REPEAT 1618 U.S. 51, Covington, TN 38019	(901) 476-0333	NO IV ONLY	
Crockett County Total Licensed Agencies				
- 10 - 11 - 15 t	447 H. marshall Class Constant Tonnesson 2020	721-584-726	(AINO AI) ON 9981	
Quality Private Duty Care	9333 Park West Blvd Ste 105a , Knoxville, TN 37923-4305			
Cumberland County Total Licensed Agencies				
Gataway Home Health Clarksville	1760 Madison St. Clarksville Tennessee 37043	931-648-4576 931-920-6100	-6100 NO (IV ONLY)	
Lifeline Home Health Care	2109 Park Plaza Dr #200, Springfield, TN 37172	4		
Meritan, Inc.	4700 Poplar Avenue, Suite 400, Memphis, TN 38117	(901) 766-0600	ON	
Highpoint Homecare	555 Hartsville Pike, Gallatin, TN, 37066	(615) 328-6695	ON	
Guardian Home Care of Nashville, LLC		615-771-2080	NO (IV ONLY)	
Davidson County Total Licensed Agencies				
			C	
American National Home Health DeKalb County Total Licensed Agencies	95 Signature Pl, Lebanon, in 3/087	(012) 433-1029		
Regional Home Care - Dversburg	1937 Cook St. Dyersburg, TN 38024	(731) 287-2307	NO (IV ONLY)	
Methodist Alliance Home Care	6400 Shelby View Dr #101, Memphis, TN 38134	(901) 516-1999	ON	
Baptist Home Care & Hospice - Covington	1618 U.S. 51, Covington, TN 38019	(901) 476-0333	ON	
Dyer County Total Licensed Agencies				
Whose the Boat is	760 Great Dake Rd Eads TN 38028	(901) 867-1556	ON	
Accredo Health Group Inc	1640 Century Center Pkwy #110. Membhis, TN 38134	(901) 385-3600	ON	
Baptist Trinity Home Care	6141 Walnut Grove Rd, Memphis, TN 38120	(901) 767-6767	NO (IV ONLY)	
Best Nurses Inc.	6061 Apple Tree Dr, Memphis, TN 38115	(901) 797-9111	ON	
Family Home Health Agency	741 Adams Ave. Memohis. TN 38105	(901) 575-8750 DISCONNECTED	R	
Functional Independence Home Care, Inc.	270 German Oak Dr. Cordova. TN 38018	(901) 363-6046	ON	9
Home Health Care of West Tennessee. Inc	2995 APPLING RD SUITE 102, Bartlett, TN 38133	(866) 824-8174	ON	:2
Homechoice Health Services	1310 E College St, Brownsville, TN 38012	(901) 476-2411	ON	6
Interim Healthcare of Memphis, Inc.	2620 Thousand Oaks Blvd, Suite 1400, Memphis, TN 38118	(901) 761-5000 (901) 767-0972	7-0972 NO	а
No Place Like Home, Inc	354 New Byhalia Rd, Collierville, TN	(901) 853-3999	ON	m
Fayette County Total Licensed Agencies				
Marine Benjaca Home Services	830 Hatcher In Columbia TN 38401	(931) 490-4600	OX	
Quality First Home Care	500 S James Campbell Blvd, Columbia, TN 38401	(931) 540-0062	ON	
Giles County Total Licensed Agencies				
Hometown Home Health Care Inc	121 Forest Hills Rd. Rogersville. TN 37857	(423) 272-7941	NO (IA ONLY)	

Greene County Total Licensed Agencies					
Magnolia Regional Health Care Home Hospice	2034 E Shiloh Rd, Corinth, MS 38834	(662) 293-1405		NO	
Hardin County Total Licensed Agencies					
Sweetwater Hospital Home Health	304 Wright Street, Sweetwater, TN 37874	(865) 213-8508		ON	
Loudon County Total Licensed Agencies					
Regional Home Care Parkway					
Obion County Total Licensed Agencies					
Americare Home Health Agency, Inc	3949 Whitebrook Dr, Memphis, TN	(901) 345-5853		(NO ANSWER)	
Still Waters Home Health Agency	856 Willow Tree Cir, Cordova TN	(901) 794-7988		ON	
Shelby County Total Licensed Agencies					
Unicoi County Home Health	100 Greenway Cir, Erwin, TN 37650	423 431 6146	(423) 743-1244	ON	
Unicoi County Total Licensed Agencies					
At Home Healthcare	4711 Trousdale Drive, Suite 129, Nashville, TN 37220	615.988.2604	615.891.4326	ON	
Williamson County Total Licensed Agencies					

SUPPLEMENTAL #1

135

July 28, 2014 9:26 am

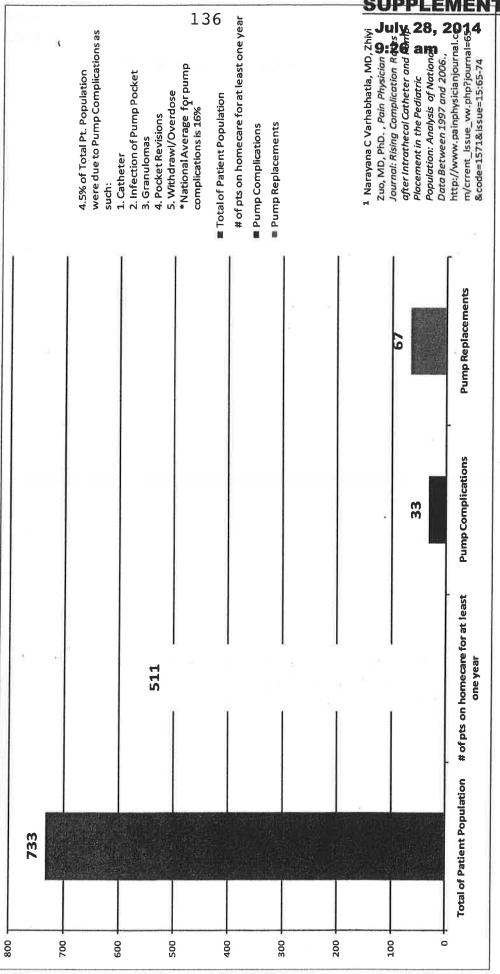
Attachment C.Need-Item 1.b.

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Specializing in The Management of Pain and Spasticity Implanted Pump Therapies

Pump Complications in Homecare Compared To National Averages Chart 1

IMPLANTED PUMP MANAGEMENT, LLC.



SUPPLEMENTAL #1

July 28, 2014 9:26 am

July 24, 2014

To Whom It May Concern:

This letter is written in regards to the need for more home intrathecal infusion services in the state of Tennessee.

I have an implanted intrathecal pump and a homecare option is definitely the best for me and my family.

Please consider allowing more companies to introduce intrathecal home management services to better serve the individuals of Tennessee.

Sincerely,

Bonn Flut

Bonnie Flint 120 Brookwood Lane Apt 20 Gainesboro, TN 38562

SUPPLEMENTAL #1

July 28, 2014 9:26 am

July 24, 2014

To Whom It May Concern:

This letter is written in regards to the need for more home intrathecal infusion services in the state of Tennessee.

I have an implanted intrathecal pump and a homecare option is definitely the best for me and my family.

Please consider allowing more companies to introduce intrathecal home management services to better serve the individuals of Tennessee.

Margaret Stacey
Lebanon, TN 37090

139

July 28, 2014 9:26 am

Attachment C. Economic-Item 10.a.

2:29 PM

07/24/14

Accrual Basis

IMPLANTABLE PUMP MANAGEMENT

Balance Sheet

July 28, 2014 9:26 am

As of June 1, 2014

	Jun 1, 14
ASSETS	
Current Assets	
Checking/Savings	4 445 07
IPM, LLC - ELECTRONIC VALLEY IPM, LLC - CASH VALLEY	1,445.07 131,069.45
Total Checking/Savings	132,514.52
Total Current Assets	132,514.52
Fixed Assets	
Accumulated Depreciation	-7,365.12
Equipment	29,995.08
Computer/Phone Software	16,250.00
Total Fixed Assets	38,879.96
TOTAL ASSETS	171,394.48
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Other Current Liabilities	400 400 44
Shareholder Loan	102,488.44
Total Other Current Liabilities	102,488.44
Total Current Liabilities	102,488.44
Long Term Liabilities	
Due to Basic Home Infusion, Inc	9,405.00
Total Long Term Liabilities	9,405.00
Total Liabilities	111,893.44
Equity	
Retained Earnings	7,534.80
Net Income	51,966.24
Total Equity	59,501.04
TOTAL LIABILITIES & EQUITY	171,394.48

141

SUPPLEMENTAL #1

July 28, 2014 9:26 am

Attachment C. Economic-Item 10.b.

2:44 PM

07/24/14 **Accrual Basis** IMPLANTABLE PUMP MANAGEMENT July 28, 2014 **Profit & Loss**

9:26 am

June 2014

	Jun 14
Ordinary Income/Expense Income	425.00
Fee Refunds	125.00
Total Income	125.00
Expense Filing fees Bank Service Charges Insurance Licenses and Permits Printing and Reproduction Rent Telephone Utilities Water	3,000.00 177.01 1,409.48 3,455.00 89.43 1,557.08 342.26
Total Utilities	10.60
Total Expense	10,040.86
Net Ordinary Income	-9,915.86
let Income	-9,915.86

143

SUPPLEMENTAL #1

July 28, 2014 9:26 am

Attachment C. Economic-Item 10.c.





STAYEMENT OF ACCOUNT 9:26 am

IMPLANTED	PUMP	MANAGEMENT	LLC
1401 VALLE	Y RD		
MAUNTE NIT C	7470	2027	

Page:

1

Chks Paid: Statement Date:

10 06/30/14

Account Number:

41577485

Indicate to the right any changes of address. Cut at the dotte	ed
line and return this form to: Valley Customer Service,	
1445 Valley Road, Wayne, NJ 07470	

Street:	
City, State, Zip:	
Signature:	

**************** BusinessCHECKING 300 41577485 *******************

Checks in Order

Date_Number_	Amount	Date !	Number	Amount
06/06 1086	250.00	06/16	1099	89.43
06/13 1087	1,000.00	06/16	1100	622.33
*		06/16	1101	172.14
06/20 1095	120.00	,	k	
*		06/24	1106	10.60
06/06 1097	250.00	06/24	1107	451.68
06/17 1098	1.557.08		- -	

(*) Check Number Missing or Check Converted to Electronic Transaction and Listed Under Non-Check Transactions

Daily Balance Summary

Date	Balance	Date	Balance	Date	Balance
05/30	136,339.45	06/16	133,955.55	06/24	131,816.19
06/06	135,839.45	06/17	132,398.47	•	,
06/13	134.839.45	06/20	132 279 47		

Account Summary

Previous Statement Date: 05/30/14

		,						
Beginning			In	terest		Service		Ending
Balance	+	Deposits	+	Paid -	Withdrawals -	Charge	=	Balance
136,339.45	~	.00		.00	4,523.26	. 00		L.816.19

Statement from 05/31/14 Thru 06/30/14 YTD Interest Paid .00

Report lost or stolen Valley Check Card to: 888-379-9903

800-522-4100 valleynationalbank.com





July 28, 2014 9:26 am

Attachment C. Contribution-Item 7.a.

145

Synchromed Patient Visit Procedure

SUPPLEMENTAL #1 July 28, 2014

9:26 am

I: <u>Purpose</u>: To establish guidelines to ensure safe, thorough and consistent assessments and procedures for skilled nursing visits. To ensure patients continuity of care with all of Implanted Pump Management RNs.

II: Applicable Documentation/References

P.C. 02.01.01/P.C. 02.01.03/P.C. 02.01.05/P.C. 02.02.01

P.C 01.02.05/JCAHO Standards

III: Policy: All Implanted Pump Management RNs will follow established basic guidelines for skilled nursing visits. Documentation must be done on patients visit note if for any reason the procedure is not followed.

Procedure:

- RN will verify impending visit via a telephone call 3-5 days before visit.
- Upon arrival of patient to infusion center, RN will verify patient name and scheduled appointment.
- RN will wash hands before patient contact has been made.
- A full physical assessment will be done on patient if more than one month has lapsed since last assessment, or a refill is to be performed.
- If medication is to be infused, RN will thoroughly inspect medication, syringe and kit for the following:
 - *Correct Patient
- *Syringe cap intact
- *Correct Medication
- *Syringe cap color correct
- *Correct Concentration
- *Syringe hub intact
- *Correct volume
- *Correct refill kit
- *Clarity of medication
- *Expiration date
- *Any ancillary supplies
- -A telemetry reading pump status check is to be done to verify MD orders.
- -RN may proceed with refill after all checks are completed, and/or may proceed with dose adjustment.
- -A final telemetry update is to be done after refill or adjustment to update all new values.
- -A copy is to be printed, reviewed with the patient and sent with the patient.
- -Alarm date is to be discussed with the patient and an appointment is to be made for the next refill, 1-5 days before alarm.
- -Garbage is to be disposed of in appropriate garbage receptacle and sharps in sharps container.
- -RN to wash hands.

147

SUPPLEMENTAL #1

July 28, 2014 9:26 am

Attachment 28-Publication

July 28, 2014 9:26 am



435 Montbrook Lane Knoxville, TN 37919

Voice (865) 584-5761 Fax (865) 558-8687 or (865) 584-6513 (Acctg)

AFFIDAVIT

Implanted Pump Management 1401 Valley Road Wayne, NJ 07470

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the list of newspapers on the date (s) stated therein as authorized by your office.

As requested, full page tearsheets are submitted herewith on our invoice S14.3160 as further proof of publication.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Third day of July 2014

Kathy Helisley, Accounting Services Representative

TENNO MANUAL PONO TMA Sworn before me this 23rd day of July 2014

Earl Goodman, Notary Public

ADDITIONAL INFORMATION FOR SUPPLEMENTAL - #1 -COPY-

IMPLANTED PUMP MANAGEMENT

CN1407-027

July 30, 2014 9 :54 am

Denny Douglas Castillo

8500 Summerfield, NC 28078 Cellular (704) 718-2875

Therapy Consultant for Intrathecal Pump Therapies

PROFESSIONAL EXPERIENCE

MEDTRONIC NEUROMODULATION Therapy Consultant

- 15 years of experience in educating the medical community and consulting hospitals
 and accounts on all aspects of Medtronic neuromodulation therapies. Assisted
 accounts in setting up programs to offer pump implantation and assisted
 communities in setting up systems to safely manage pumps post implant.
- Experienced in training facilities, staff and patients on the operation, features and benefits of all aspects of pump therapy apparatuses.
- Strong relationship skills and ability to interact effectively with surgeons, physicians, nurses, pharmacists and all members of the health care team.
- Proven ability to effectively negotiate and collaborate with medical practices, hospitals and health care companies.
- Experienced in setting up hospital therapy programs. Adept at setting up administration meetings and assisting practices from start to finish in developing Targeted Drug Delivery programs.
- Clinical care experience in hospital, home care, infusion and office settings –firm understanding of medical and pharmaceutical terms, conditions, treatments and protocols.
- Experienced in training surgeons, ancillary care and administration in all aspects of pump implant, management and troubleshooting.

GASTON MEMORIAL HOME HEALTH CARE, Gastonia, NC

1995-2001

Registered Nurse - Infusion specialist - Case Manager

Managed all aspects of home care for patients requiring intravenous infusion therapy

- Ongoing coordination of care with multiple physicians, pharmacists and ancillary staff.
- Instructed staff, patients and families on medical device use, procedures and techniques. Administered nursing care and educated on disease entities and treatment protocols.
- Assisted in establishing infusion service contracts at infectious disease and rheumatology offices. Assisted in management and provided infusion skills for administration of Remicade and multiple infusion medications.
- Assisted in recruiting and training all infusion team staff.
- Helped maintain and train a twenty-four hour infusion on-call team.
- Utilized as a mentor for undergraduate and RN to BSN students and infusion training for 100 employee home care systems

July 30, 2014 9:54 am

FIRST AMERICAN HOME CARE, Battle Creek, MI Case-manager.

1994-1995

Carried out case management duties while assisting in staff training and community networking for new branch office.

BATTLE CREEK HEALTH SYSTEM, Battle Creek, MI

1993-1994

Critical Care Unit (cardiac/surgical)

Rotated as charge nurse. Member of "Code team" and assisted on all in hospital cardiopulmonary resuscitations. Accompanied ambulance staff on critical care patient transports.

Active in staff development. Prepared and presented oral motivational presentation for 120 employees on positive attitudes and optimism in a changing health care

system.

EDUCATION

Bowling Green State University, Bowling Green, OH in consortium with the Medical College of

Bachelor of Science in Nursing, 1993

Chosen for 12-week internship at Saint Lukes critical care unit following highly competative selection process.

Resident advisor for 120 dormitory college students 3 years at BGSU.

Earned athletic scholarship for Bowling Green State University in division 1 baseball. Financed 100% of college through Castillo painting business in off time.

Don Donnelly Regional Director of Flowonix Medical in TN November 2013 – Present

Flowonix is a medical device company dedicated to helping those who suffer from chronic disorders. Our team has decades of experience developing unique and reliable medical devices to improve lifestyles. Using one of a kind technology, Flowonix has developed an implantable drug pump designed to deliver therapeutic drugs into the spine to relieve a variety of chronic disorders and help patients return to normal lives.

Regional Sales Director - Mid-South Region

St. Jude Medical

July 2009 – January 2014 (4 years 7 months)

Manager, Sales Training

St. Jude Medical

July 2008 – July 2009 (1 year 1 month)

Marketing Manager of Field Support

St. Jude Medical

January 2006 – July 2008 (2 years 7 months)

Territory Manager

St. Jude Medical

January 2004 – January 2006 (2 years 1 month)

Dr. Melissa King **Smokey Mountains District** Medtronic Neurological 710 Medtronic Parkway Minneapolis, MN 55432

Dr. King is a member of Medtronic's Neurological division. The treatment of pain and spasticity utilizing intrathecal baclofen therapy is one of her areas of expertise.

Biomedical Field

Medical technology for neurological disease

Business

Manufacturing and Service

Products

Neurological and Spinal Therapeutic Devices and Technologies

Activa® tremor control therapy Advanced pain therapies (APT) Enterra therapy Hepatic arterial infusion (HAI) therapy InterStim® therapy for urinary control Intrathecal baclofen (ITB ****) therapy

Medtronic PS Medical

Medtronic Functional Diagnostics

Services

Medtronic, Inc. is engaged in medical technology. The Company functions in seven operating segments that manufacture and sell device-based medical therapies. Its operating segments include Cardiac Rhythm Disease Management (CRDM); Spinal and Navigation; Neurological; Vascular; Diabetes; Cardiac Surgery, and Ear, Nose and Throat (ENT). In April 2007, the Company formed Medtronic Cardio Vascular, a new global business combining the Company's existing Vascular and Cardiac Surgery businesses.

July 30, 2014 9 :54 am

PROOF OF PUBLICATION

	Newspaper	Total Counties
1	Bristol Herald Courier	6
2	Buffalo River Review	3
3	Chattanooga Times Free Press	16
4	Clarksville The Leaf Chronicle	1
5	Commercial Appeal	16
6	Cookeville Herald Tribune	7
7	Dyersburg State Gazette	5
8	Greeneville Sun	3
9	Jackson Sun	6
10	Johnson City Press	7
11	Kingsport Times-News	6
12	Knoxville News Sentinel	17
13	McMinnville Southern Standard	4
14	Murfreesboro Daily News Journal	5
15	Paris Post Intelligencer	4
16	Rogersville Review	6
17	Tennessean	29
18	Union City Messenger	3 = 11 d = 4 = 11 = 12 = =

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Bristol Herald Courier* with circulation and coverage within the following counties: Johnson, Carter, Sullivan, Washington, Greene, and Hawkins (6 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

Classified Marketplace

Check Out today's new classified ads by seeing the red check in each new ad.



(m) LEGALS

LEGAL NOTICES

Notice is hereby given that Richardson Ambu-lance Service LLC, 1111 South Main Street, Marion, VA 24354, has submitted to DMV an application for a certificate of public cover-lence and necessity, authorizing passenger transportation as a common carrier over ir-regular routes.

If granted, the certificate will only authorize passenger transportation between points in the Counties of Smyth, Washington, and Wythe, Virginia.

Any person who wishes to support or oppose the application, but does not wish to be a par-ty to the matter, may submit a written state-ment to DMV Motor Carrier Services Operat-ing Authority Case Management, P. D. 80 77412, Richmend, VA 22265-001. The state-ment must be signed and contain the applia-ment must be signed and contain the applia-tion of the signed and contain the applia-d (Activa0071E3).

Any person who wishes to protest the applica-tion and be a party to the matter must con-tact DMV Motor Carrier Services Operating Authority Compliance Management at (804) 367-6504 to receive information on filling a pro-

The deadline for submitting letters of sup-port, opposition, or protest is Friday, July 18, 2014 (must be postmarked on or before).

Legal Notice

Time Warner Cable's agreements with programmers and broadcasters to carry their services and stations routinely expire from time to time. We are usually able to obtain renewals or extensions of such agreements, but in order to comply with applicable regulations, we must inform you when an agreement is about to expire. The following agreement is about to expire. The following agreements are due to expire soon, and we may be required to cease carriage of one or more of these services/stations in the near future: Youtoo, Outdoor Channel

In addition, from time to time we make cer-tain changes in the services that we offer in order to better serve our customers. The fol-lowing changes are planned:

Starz will ofter a free preview August 8-10, 2014. It is available to all digital subscribes and may contain PQ. PG-13, TV-14, TVA and R rated programs. To find out how to block this preview and for more parental control information, visit two.com or call

TRUSTEE SALES

NOTICE OF SUBSTITUTE TRUSTEE'S SALE OF 27397 Rivermont Drive, Ablagdon, Virginia 24211 (Washington Co., VA)

In execution of a deed of brust, from DAVIO TRAVIS SINGLETON, dated June 22, 2007, in the principal amount of \$122,736.3, recorded in the Clerk's Office of the County of Washington, Virginia, as Instrument Number 07000529, (Set he. Tweny, P.C. having been appointed Substitute Trustee under instrument of record in said Clerk's Office as instrument Mumber 14000223), due to default in payment of the debt secured, the undersigned Substitute Trustee wild offer for said at public auction in front of the County, but on the 17th Captain of the County Machinery of the County of the Clerk's Office as a set of the County of the County

Abingdon, Virginia 24211 situated in the County

Ablingdon, Virglinia 24211 situated in the County

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide follical studies to be feedably foreign and distincted parties, is accordance
with T.C.A.; 46:1-1:601 et seq.. and the facts of the Health Services and Development Agency, dual implanted Funge
which T.C.A.; 46:1-1:601 et seq.. and the facts of the Health Services and Development Agency, dual implanted Funge
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TRUSTEE SALES

TRUSTEPS SALE OF 11587 Goose Creek Road

TRUSTEPS SALE OF

11587 Goose Creek Road

Bristol, VA 24202

In execution of a Deed of Trust in the
original principal amount of \$183,673,00,
dated October 31, 2011, recorded among
the land records of the Circuit Court for
Washington County on November 1, 2011, as
instrument Number 110005612, at Page
86, the understipned appointed Substitute
Trustee will offer for sale a public suite for
the Circuit Court of Washington County, 189
E Main St, Alingdon, Va An Aspust 8, 2814
at 10:09 AM, the property described in said
deed of trust, located at the above address,
and briefly described as BEING LOT NO. 5
OF THE SUBBUYISION OF ROBERT E. COCKE
AND PAUL H. COCKE LAND NEAR WALLACE,
WIRDING, AS STOWN ON SURVEY MADE IN
OF WHICH IS OF RECORD IN THE CIRCUIT
COUNT CLERKS OFFICE FOR WASHINGTON
COUNTY AT ABINGDON, VIRGUINA, IN MAP
BOOK, T, PAGE 31, TO WHICH REFERENCE IS
HEREY MADE FOR A MORE PARTICULAR
DESCRIPTION THEREOF, SAU DIAM 5.
ESTED OF GOOSE CREEK ROD ANT
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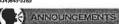
of Washington, Virginia, being more particularly described as follows: All that certain lot or parcel of lank known and designated as Lot No. (9) as shown on plat of the John A. Hanner, Jr. Property of record in the Clerk's Office of the Circuit Court of Louis Court of Louis

Included with the sale is a 2003 Southern Manufactured Home • VIN No. DSD4AL40556AB.

Sale subject to all conditions, restrictions, reservations and easements, if any of record and now applicable thereto.

Terms: At least 10% cash on day of sale; balance due within 30 days.

FOR INFORMATION CONTACT: Seth E. Twery, Esq. Seth E. Twery, P.C. P.O. Box 185 Lynchburg, VA 24505-0185 (434)845-5285



LOST

LOST POODLE: White, female, about 125s., last seen Woo-Sawell Rd. Bristol, VA off of Lee Huy exit 18 on Saturday 6/14. Please call: 276-591-3138

REWARD Missing female Yorkle, Brsitol Caverns Hwy 6/10 Contact (423) 573-5669 Running out of storage space? Sell it in the classifieds!

3 Family Garage Sale Wed. & Thur, Eam-2pm 321 Wimberly Way Bristol, Th near Akard School • Blountville Hwy



Small used auto parts business for lease. Serkous inquiries only, Send contact Information to PO Box 3273, Bristol TN 37620

MERCHANDISE ANTIQUES

Their Store closing any Stiff Everything must got, Yard Sale Prices! 11:30a 5:30p Thursday, 8:30a-5:00p Friday & Saturday. 1713 Edgewort Avenue.

FURNITURE & HOUSEHOLD ITEMS

MISCELLANEOUS FOR SALE

CLEARANCE WIGS, 50-70% off! Universal P 411 Gate City Hwy, Bristol VA 276-669-8131

TREASURE SEEKERS

Hutch- Solid cherry dining hutch. Good Condition. \$900 Call: 606-422-2318

RECIREATION

CAMPERS & TRAVEL TRAILERS

YARD & ESTATE SALES CAMPERS & TRAVEL TRAILERS



Large Lighted Glass Curio Cabinet, Drazel Corner Hutch, Sofa table, Retail Store Deplays and Shelving, and Assorted occasional Lables 7111 Edgenord Avenue, 1120a 5:00 Throday, 8:004-5:00p Friday & Saturday,

LAWN & GARDEN EQUIPMENT

John Deere Manure Spreader model M51105G, 50 Bushels perfect condition. Call anythme 276-525-5374, Asking \$3850

FREE ADS

BOATS

2000 Crestliner 17 ft. aluminum fishing boat with a 50 hp Johnson motor with traller, 2 livewells, lock boxes, & lisher finder. Excellent Condition. \$3,600 Call: 276-619-3726



wave, fridge, freezer, 2 propane tarks, new bat tery, all in good cond. 57,500. 423-764-669 2011 Fleetwood Boun-der Classic, 2 sides, 15k mi, perfect cond., all options & full warr. 10/17 or 60h ml. Ford VIo, Blue Ox & tow veh. aval. 564,900 (MSRP 5110K+) 423-646-2647.

MOTOR HOMES & RVS



331, 2004, 17K miles.

EMPLOYMENT

ACCOUNTING & FINANCE

POSITION AVAILABLE Mt. Cap, Inc is Marion, VA will be accepting applications for the position of Executive Different Programme Continued Transport of Executive Different Programme Committee and Programme Committee and Programme Committee Committ

CUSTOMER SERVICE



EXIT 19, ABINGDON
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CAMPER OR BOAT THAT YOU NEED TO SELL? To Advertise Call 276-645-2525

ME PREDICTion better sales 1 when you advertise in the Classifieds!!

Foreclosure Auction By Order of Secured Party

Highly Visible Convenience Store 1831 Hwy. 126, Bristol, TN



- Approx. 3,040 sq. ft. Build-ing on Approx. 0.52 Acre Lot Built in 1970. Two Fueling Islands with Corner Lot at Intersection of Hwy. 126 & Plalinview Dr. Approx. 346 Frontage on Special System

Furrow Auction Co. 865.546.3206 • www.furrow.com • TN Lic. #62

CLASSIFIED ADVERTISING HOLIDAY DEADLINES

Due To the Independence Day Holiday, the following Advertising Deadlines will be in effect:

- IN COLUMN LINE ADS -

ADS FOR: DEADLINE: FRIDAY, JULY 4.....WEDNESDAY, JULY 2 - 4:00 PM SATURDAY, JULY 5THURSDAY, JULY 3 - 9:00 AM SUNDAY, JULY 6.....THURSDAY, JULY 3 - 12 NOON MONDAY, JULY 7.....THURSDAY, JULY 3 - 1:00 PM

- CLASSIFIED DISPLAY -

ADS FOR: **DEADLINE:** FRIDAY, JULY 4......WEDNESDAY, JULY 2 - 9:00 AM SATURDAY, JULY 5 ... WEDNESDAY, JULY 2 - 10:00 AM SUNDAY, JULY 6......WEDNESDAY, JULY 2 - 2:00 PM MONDAY, JULY 7 WEDNESDAY, JULY 2 - 3:00 PM TUESDAY, JULY 8..... THURSDAY, JULY 3 - 2:00 PM

★ THE CLASSIFIED ADVERTISING DEPARTMENT WILL BE CLOSED FRIDAY, JULY 4, 2014 ★

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Chattanooga Times Free Press* with circulation and coverage within the following counties: Hamilton, Meigs, Bradley, Moore, Franklin, Coffee, Grundy, Marion, Sequatchie, Van Buren, Bledsoe, Rhea, Cumberland, Roane, McMinn, and Polk (16 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

LEGAL NOTICES

F6 • Wednesday, July 2, 2014 • • •

BICYCLES

chwinn Bike, Mans new, 26° no gears \$75, 706-638-1103. Ichwinn Bike, 28° Mens, 7 speed, like new, 880, 423-875-8911. HEK Bicycle, new, 20" 7 speed, idden Iwice, \$200, 423-855-1628

Greet New York Floe Market Move-to special (new vendork only) Cas 705-850-0189 FLEA MARKETS

FUEL

BUILDING MATERIAL

2 Garage Doors 10' w/cpsners \$150 423-322-3665 BRICK PAVEN Solid, Red, 3.549', 1920s tritle brick \$.65 240-0153

BLY BLY FARWOOD SOI Harrood, WHIETT KSTRI SSOINE NV proc., 429-913-2553

Compared countries, a year of additional confidence of the organic processing of the organic processing of the organic processes \$500 occupant (or organic processes \$500 occu

1800-1898, \$250, 423-463-0443.

FURNITURE

(Itchen Sink, new, never installed, block, \$75, 423-888-0542.

PAINT - new load Various Colors \$5 per gallon, 423-999-1414

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Stow Cooker, west bend 6 quart. House note, \$15.423-659-53.2 Bugar and creamer, aler of devid. \$5.00.425.306-5240

Surplue Kit/Bath Cabinets New solid wood 55450 have more cash will sap 269-8257

Patents on unit-\$500, \$700.5 (Opt. Patents (Opt. Patents on Unit-\$500, 457) \$250,557. (Conference - Instants & Sept. \$373) \$700,4870 (Opt. Patents & Sept. \$477,016 or Execution Conference on Confere First Act youth guiler 2 sees strings witnes \$25 423-677-0209 MUSICAL MERCHANDISE AMO, Janussin Spiner, good cond Spinith: 81 sense \$100, 499-9924



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LEGAL NOTICES

Fig. 100 - 1





Kitchen Inland-White \$50 423-875-3185



Golden Reinkiwe puspida ANC row Walling dec. M. & F. golden color \$500 & Eng. cream \$700 226-676-676-676 Great Dane Pruppes 34. ANC avai. for new homes. 240-248-2587.

Rocking Horses (2) large and small, \$35 for both, 423-805-7520.

Rotary Phone, old, black, \$20, Call 422 355,7152, Shampoo Chair, \$75, Call 423-602-7302.

Morkles, CKC / UKC, shots 5 wurned, health gueranies H \$400 F \$500 705-882-8035

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SWING, with canopy, Martha Stewart, now, \$95. Call 423-877-4170. TIRES - 225/60/16 on bulck whoels, good freed, \$140 706-935-2380

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AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in Clarksville's *The Leaf Chronicle* with circulation and coverage within the following counties: Montgomery (1 county total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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July 30, 2014

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Apply orders: Highly Shift halos / Add by Constitutes or Copy Shift halos / by Capitalism

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WART A SHORT TERM OF LONG TERM OPPOSTURETY ?

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bendle, Call tester BE-BIT-613 & are 6 pm DUMP TRUCK DRIVER Experience required. Clean driving record

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Insertion Dates: June 25, July 2, 9, 16, 2014

manded in the complaint. Issued: 6-30-14 Cheryl L Castle, Clerk

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AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in Cookeville's *The Herald-Citizen* with circulation and coverage within the following counties: Putnam, Jackson, White, Overton, Clay, Pickett, and Fentress (7 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

This description is believed to be correct to our

DATE & TIME OF SALE:

best understanding.

DESCRIPTION OF PROPERTY,6 rooms, 3 bedrooms, 1 bath, 1,056 sq with crawl space.

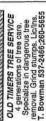
(or best offer above minimum bid)

Minimum Bid: \$30,158.00

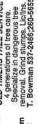
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adjourn the day of the sale to an-other day, time, and place cer-tain without further publication, upon announcement at the time and place for the sale set forth above, W&A No. 725 241436

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WILSON & ASSOCIATES, P.L.L.C., Successor Trustee

DATED June 24, 2014

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Tusies Services or TN LLC.
Substitute Trustee or its duly
appointed attentives or agents,
by virtue of the power and au.
Thursday, July T. 2014, commencing at 1:00 a.m. at the
West Entrance of the Puturan
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Courty Courthouse, Cooperation of the Puturan
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more particularly described as
follows: Being Lot No. 2:1 of
Huntington Woods Subdivision,
Phase II, as shown by plat of record in Plat Cabiner C, Silde 2.
Register's Office, Puturam
Courty, Tennessee, which is
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Molly has been missing since Tues 06/03/14 last seen in Northeast School Area, Molly was wearing a collar Call Chase 261-5524 or Becky 260-2994

FOUND on Holladay Rd Gray male tabby cat, very friendly, Call 979-2173

Comes from Latin

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NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

nay view and obtain a copy of the Petition and any other sub-sequently filed legal documents at the Juvenile Court Clerk's Of-

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All persons, resident and non-resident, having claims, ma-tured or unmatured, against the estate are required to file same with the Clerk of the above-

East door of Putnam County Courthouse FOR INFO CONTACT: 07/09/14 AT 10:30 am PLACE OF SALE:

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HEBALD-CITIZEN, Cookeville, Tenn. — www.herald-citizen.com — Wednesday, July 2, 2014 — B3 Letters to the Baltor
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 Like to Know Questions
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528-0426 / 265-5687

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Cookeville TN 38501 3335 Dietz Dr

This description is believed to be correct to our DESCRIPTION OF PROPERTY.6 rooms, 3 bedrooms, 1 bath, 1,056 sq with crawl space. (or best offer above minimum bid) Minimum Bid: \$30,158.00

East door of Putnam County Courthouse DATE & TIME OF SALE: FOR INFO CONTACT: 07/09/14 АТ 10:30 аш best understanding. PLACE OF SALE:

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and organizational skills a must
be computer & dictaphone experine waiter Fitzpatrick, PO Box 3347, as
Cookeville, TN 3502; FAX w
1931/526-3092; Email REG'D DENTAL ASSISTANT:
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member of a fun hardworking team of professionals? Then we would like to meet with you!
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NOTICE TO CREDITORS
ESTATE OF MARTIN SHIRREL
ALLEN, DECEASED NOTICE IS
ALLEN, DECEASED NOTICE IS
ALUNE 2014, Letters ADMINISTIETE OF MARTIN SHIRREL. AL.
LEN, GEORGES WHO died MATLEN, GEORGES WHO died MATLEN, GEORGES WHO died MATATH ZOTO 4 were issued to the undersigned by the Probate Court
of Putina Court, Tentessee.
All persons, resident and nonresident, having claims, matured or unmatured, against the
estate are required to file same
with the Clerk of the abovenamed Court on or before the
sariler of the dates prescribed in
(1) or (2) otherwise their claims
will be forever barred;

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ject to all matters shown on any | Call 528-9715 for more information. NOTIFICATION OF INTENT TO APPLY 9:00 a.m. for the Hearing on the Perition field by the State of Tennessee. Department of Children's Services I you fall to do so, a default judgment will be taken against you for the relief demanded in the Perition. You may view and obtain a copy of the Perition and any other subsequently filed legal documents at the Juvania Court Clerk's Office, Cookeville, Tennessee.

FOR A CERTIFICATE OF NEED

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Dyersburg State Gazette* with circulation and coverage within the following counties: Dyer, Crockett, Lauderdale, Lake, and Obion (5 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

afely after it occeers to and paper and report at once at PHONE:285-4091 FAX:286-6183

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COSMETOLOGY INSTRUCTOR POSITION ANNOUNCEMENT

The Tennessee College of Applied Technology-Newbern is accepting applications for the position of Associate Instructor in the Cosmetology program at the Newbern campus.

Minimum Qualifications:

Formal instruction from an approved School of Cosmetology required. Candidate must have an active Tennessee license as a Cosmetology Instructor and a minimum of three years of successful employment as a licensed Cosmetologist. Teaching experience preferred. The successful candidate must also be able to teach all phases of cosmetology. Must possess good verbal and written communication skills and be able to relate to students and the public. Proficiency in the Microsoft Office suite required. Superior organizational skills will be necessary to oversee the program development and the implementation of this program.

The Associate instructor of Cosmetology is responsible for teaching all phases of the Cosmetology program to include sterilization, sanitation, and bacteriology; shampooling, rinsing and styling; hair and scalp care; manicuring and nail care; hair shaping; permanent waving; facials, arching, lash and brow tinting; hair coloring, bleaching, toning and lightening; anatomy, physiology, and chemistry; shop ethics, interpersonal skills, and sales; Tennessee Cosmetology Law; finger waving and pin curls; blow drying and curling irons; permanent waving; hair relaxing; dispensing supplies and desk operations; and computer salon applications. Must be able to coordinate practical experiences and manage patron services. Instructor must participate in professional development activities as needed to learn new techniques and trends in the industry. Other duties include collecting live work fees and reconciling cash deposits, curriculum development, student recordkeeping, student recruitment, placement and follow-up of program graduates, and budgeting.

Salary: Commensurate with education, experience, and TCAT salary guldelines.

Application Process and Deadline: Applications can be downloaded from www.tcatnewbern.edu under the Home/Career Opportunities menu. Review of applications will begin immediately upon receipt and continue until position is filled.

Submit Application and Resume to:

Tennessee College of Applied Technology-Newbern (Attn: Debbie Harris) 340 Washington Street Newbern, TN 38059

The Tennessee College of Applied Technology - Newbern is an AA/EEO employer and does not discriminate on the basis of race. color, national origin, sex, disability, or age in its programs and activities. The following person has been designated to handle Inquiries regarding the non-discrimination policies: Donnie Walton, Asst. Director, 340 Washington Street, Newbern, TN, 38059. 731-627-2511, dwalton@tcatnewbern.edu.

A Tennessee Board of Regents Institution

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

NOTIFICATION OF INTENT TO

APPLY FOR A CERTIFICATE OF NEED

This is to provide efficial notice to the Health Services and Development Agency and all interested parties, in accordance with E.I. E.A. § 68-11-1601 et 22-42, and the Rules of the Hungh Menagement, LLC owned by Ray Rules of the Hungh Menagement, LLC owned by Ray Putrino with an ownerthip type of Single Member LLC and to be tannaped by Ray Putrino incode to file an application for a Certificate of Need for the setablistancies of a home-care organization and the initiation of feature health services limited to introduced purpose science. The entimated project cost in \$5.1001. The agency will utilize one officie, Location 1200 Frongester countries littled as follows: Anderson, Berford, Berton, Bledwe, Blount, Bradley, Campbell, Cannon, Caroll, Carter, Chentham, Chester, Clabbrace, Clay, Cocke, Coffee, Crockett, Cumbettand, Davidson, Decentre Dekalls, Dickson, Dyer, Payette, Fentures, Franklin, Glibson, Giller, Grainger, Greene, Grundy, Hamblen, Harolino, Huncock, Hardennan, Hardin, Hawkins, Haywood, Henderson, Herry, Hielman, Houston, Humphreys, Jackson, Jefferon, Johnson, Rans, Lake, Lunderdile, Lawrencee, Lewis, Lincola, Loudon, McMinn, McNairy, Maccoe, Madison, Masshal, Master, Majer, Moncoe, Montgomer, Martin, Masshall, Master, Majer, Moncoe, Montgomer, Martin, Masshall, Master, Majer, Moncoe, Montgomer, Martin, Masshall, Master, Majer, Moncoe, Montgomer, Warren, Wahington, Wayse, Waster, White, Williamone, Willion, The anticipated due of filing the application is fully for the conductive of the publication in American development Agency, Andrew Parker, Scholley, Spring, Parker, Scholley, Chesco, Chemican, Chesco, Chemican, Charles, Parker, Scholley, Spring, Parker, Scholley, Chemican, Scholley, Martin, Martin, Hawkins, Haywood, Henderson, Hend

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No resumes/applications/phone calls will be accepted at No Individuals may apply at the Sikeston Career Center.

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Competitive starting salary, plus a variable compensation program, a comprehen medical plan, 401k and pension.

To Apply:

Call the Sikeston Career Center 573-472-5250

To avoid a long wait time, the Sikeston Career Center recommends you schedule an appointment before coming into the office to apply and complete the required testing; please call 573-472-5250 to schedule an appointment.

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www.FedEx.com/careers Select US, then FedEx Freight and search by Job #400754.

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TN 38059

RECRUITER POSITION ANNOUNCEMENT

The Tennessee College of Applied Technology-Newbern is accepting applications for the position of Recruiter,

- Bachelor's Degree from an accredited four (4) year college preferred;
 Snerifite engages in a Transition of the Property of the Proper
- Specific experience in a Tennessee College of Applied Technology is: highly desired;
- Applicants must have good multitasking, organization, communication, and planning skills;
- Must have the ability to establish and maintain effective networks. with high schools, colleges, prospective students, faculty, staff, and the general public;
- Software skills should include Microsoft Word, Excel, and PowerPoint or Publisher:
- Ability to work as a part of a team oriented organization.

Job Description:

- Assist prospective students' enrollment needs
- Responsible for new student orientation
- Responsible for getting students ready to enroll each enrollment period
- Assists with the development and maintaining of marketing materials, newspaper/web articles, advertisements, and social media
- Attends recruitment functions of high schools, colleges, community fairs, etc.
- Works with area high schools (CTE programs, guidance counselors, and teachers) for various dual credit and college ready
- Organizes school tours and visits
- · Hosts recruiting fairs throughout the year to attract new students
- Develops networks with community agencies to bring TCAT programs to the attention of their clients
- Maintains a student tracking system and keeps accurate records of all students who express an interest in TCAT programs
- Conducts information sessions on admissions requirements for potential students
- Completes various reports
- Career Counseling
- Collaborates with local TBR community colleges
- Maintains student waiting list

Salary: Commensurate with education and experience and according to salary guidelines established by the Tennessee Board of Regents.

Application Process and Deadline: Applications can be downloaded from www.tcatnewbern.edu under the Home/Career Opportunities menu. Review of applications will begin immediately upon receipt and continue until position is filled. Completed applications can be mailed or delivered to:

TCAT-Newbern Debble Harris 340 Washington Street Newbern, TN 38059

The Tennessee College of Applied Technology - Newbern is an AVEEO employer and does not discriminate on the basis of race, color, national origin, sex, disability, or age in its programs and activities. The following person has been designated to handle inquiries regarding the non-discrimination policies: Donna Hastings, Director, 340 Washington Street, Newbern, TN, 38059, 731-627-2511, dhastings@tcatnewbern.edu.

A Tennessee Board of Regents Institution

166

July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Greeneville Sun* with circulation and coverage within the following counties: Greene, Washington, and Hawkins (3 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

Wednesday, July 2, 2014

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Public Notices WHEREAS, NANCY R. KESTEPSON, avia NANCY KESTEPSON, of Greene County, Tennessen, executer, acknowledged and definered to Nameth Clair. Nool, Traises, to share he had not the deep CSOS, Progression and Deed Book 419A, Page 384 (see also Dood Book 50A, Page 237) at the Repisters of lice by (Greene County, Tennessee, to servine a certain indictedness owing to Washington County Bank, now around as Capital Bank, N.A., and more fully described breek; and Public Notices Public Notices TRUSTEE'S NOTICE OF SALE Public Notices Public Notices

WHEREAS, default has been made in the payment of said indebtachess and the same has become due and payeble after proper notice of default was given and the owiver and holder of seld incoltonous and additionable that the faith balance owing therein due and payable, this given notice of screteration, and has insurated the said further to incolose said frost Deed and to adventee and self the groperty therein and herein described, upon the terms and conditions set inth in said frust Deed.

NOW, THEREODE, notce is neercy given that I will on the 28th day of Jahy, 2014, at 3.45 pm, provaling standard lines in Greene County, Tennossee, at the former described another to the county Countrolland (Creene). The country of country Countrolland Creene County, Tennossee, at the following described another country, to standard the country of secondary of secondary constructions as attended in the country of secondary constructions, as attended to reference in the country of the subject deep of neal Telegraphy to the country of the subject deep of neal Telegraphy to the country of the subject deep of neal Telegraphy to the country of the subject deep of neal Telegraphy to the country of the subject deep of neal Telegraphy to the country of the subject deep of neal Telegraphy to the telegraphy to the subject deep of the telegraphy to the telegraphy to the subject deep of the telegraphy to the telegraphy to the telegraphy to the subject deep of the telegraphy to the telegraphy telegraphy

SITUATE lying and being in the 11th Givil District of Greene Courny. Tennessee and being more particularly described as follows:

Tract One:

BEGNAINS as a post on the North Side of Horton Highway, corner to Globon, and noming thereon N 09 00" E. 52; 07 test to an iorn pin, corner to Kisterson and Charaeteron terms set. An 0. 25.54. We than a fair of the the North Highway; there is with Horton Highway three (3) cuts as tollows; S. 57 45.7 W. 1. 115.55 test, S. 74 45.8 M. 15.8 M. 1. 25.4 M. 1. 25.5 M. 1. 25.5 M. 25.5 M.

with Eikfol tastem proxyes for Paul Kasteron and with Narcy Kesteron by Deed from Einer Daverpon and wide, Mario Daverport and other 2018 1858, and recorded in Deed Book 377 page 527. Pageter Oline to Chemic Dounly of Greenering, Terriessee. The sold Paul Kesteron spassed on July 13, 2002, Warning Hessand Mario Kesteron state surviving Maria by the emisches.

Fract Two:

ESERVINKE as in min put, contest cover of the Measurement and Decretel places on the New York Seatons, and serving there with the live of Paul Kelsenon N. 9 OF E. 2077 Contest on a ring not contest of Vesteron N. 9 OF E. 2077 Contest on a ring not contest of Vesteron N. 9 OF E. 2077 Contest on a ring not contest of Vesteron with fine the sea of Vesteron with the loss of Vesteron with the loss of Vesteron and One Vesteron Andreador An

AND GENAT the same property conveyed to Paul Kestinson and wife, Namcy R. Kesterson by Oeed from Flore Kesterson, diserd April 17, 1984, and recorded at People Stock Size 2560, in Peo

Located on the Subject Property and to be sold with the Subject Property is a 2005 Theward Beach Hill Mobile Home, VM No. TheFLEXPASSO433-BH13. Said Mobile Home is heapy and ASI, SWHEETE SURVINES OF METHOLOWING THE MODEL WHINGHOUS OF METHOLOWING THE METHOLOWING THE MODEL WHINGHOUS OF METHOLOWING THE M

The address of the Subject Property as shown on the lax records for Greene County, Tennessee, is 5365 Honon Highway, Greeneville, Tennessee, 37745. (Map 26, Parcel 17.02)

It will be the responsibility of the aucressful bidder to optian possession of the purporty at this expense. The eucressful bidder to responsible for any dam-gage, vanchine their bed, but the property of the sale may be subject to will be due united interference and material morts lens. No representations are made as the validity or eviderability of any theropardour of the classifications of any presentations.

kharests in the property other than the Deed of Trust being foreclosed or matters affecting title known to the undersigned include the tollowing:

1. Claim of lien against Paul Kesterson and in lenor of Robert Bianchard in the amount of \$4,700.00, recorded on December 8, 2011, and which is of necord in Deed Book 5044, page 2206, in the Register's Office for Greene County, Tennessee. (For informational purposes Robert Blanchard is decessed.)

2. Judgment len agains! Namey Koststrom and in lavor of Portoin Recovery Associates, LLC, in the amount of \$1,789.47, appearing of record in Deed Book 514.4 page 1413, in the Register's Office for Greene County, Terressee.

NOTIFICATION OF INTENT TO APPLY

FOR A CERTIFICATE OF NEED

instruction or rectifiant, Sectional Medical Activation, the supplication of Management, LLC contecting Roy Roy Partico with an ownership type of Single Management, LLC and two transcells Roy Roy Partico intends to the an application and the intends of hower levels of the caudiciplement of a house care constrained management. The satisfacts of Need for the caudiciplement of a house care care against and the intends of hower levels was received to the satisfacts of Need for the careful and careful and account of the careful and account of the careful and account of the property. Place #102 Knownie; Phys 202 Houses contained and our failure and activation, and proposed with an application of the careful and account and account of the careful and proposed and account and account of the careful and proposed and account and account of the careful and proposed and account account and account account and account acc This is to provide official notice to the Hailth Sarvices and Development Agia and all interested particul, in exactines, with T.C.A. 56 Ge-11-Gibl or seq., with the future of the Hailth Services and Jackelopment Agency, that implanted Phanagement, L.C. owned by Roy Paurito, with an ownership type of St.

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Health Services and Development Agrany, mortew Jackson Health Services and Development Agrany, mortew Jackson Health and Development Agrany, mortew Jackson Health and Development Agrany in February and Parkson Health and Corridors of Need supplication must like written motion with the Lestal Services and Development Agrany on lare than filled the application in originally setroleuded Ending at which the application is of the Development Agrany to lare than filters (15) days before the regulary settleduled Health Services and Development Agrany on lare than filled Agrany and Personnel and Development Agrany to lare than filled Agrany and Development Agrany are larger than subjection and Development Agrany are larger to the application in originally settleduction (13) Agrany are resemble applications by the Agrany; at or prior to the cosmo this makes applications by the Agrany; at or prior to the cosmo this

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July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Jackson Sun with circulation and coverage within the following counties: Crockett, Madison, Gibson, Decatur, Benton, and Hardin (6 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

30, 2015. The right is reserved. AS THE INTEREST OF THE COUNTY MAY REDUIRE TO ACCEPT OR REJECT AWY AND/OR ALL BIDS. SPECI-FICATIONS AND BID FORMS WILL BE FURNISH-ED UPON REQUEST TO THE COUNTY PURCHASING OF-FICE, 1981 HOLLYWOOD DRIVE - SUITE 100, JACK-SON, TN 38305. 731,550 6221 EXT. 7 OR TO map the

o.madison.tn.us. MADISON COUNTY GOV-ERMMENT, NOR ANY OF ITS DEPARTMENTS, OFFI-CES OR AGENCIES, DIS-CRIMINATES ON THE GROUNDS OF RACE, COL-Or religion, disability, SEX, AGE OR VATIONAL MADISON COUNTY.

TN FINANCE DEPT., PURCHASING OFFICE NOTICE OF PROPOSED

In accordance with T.C.A. 67-5-2003, et suq., notice is hereby given that Johnathan Morgan Kendrick ('Offeror') has offered to purchase for \$2,750.98 cash Map & Parcel 9785-D-002:00 and Tori Estes (Offeror) has offered to purchase for \$1,400,00 cash Map & Parcel (1870-L-004.00 and for \$1,400.00 cash Mao & Paresi 07/1-G-004.00 from Madison Coun-

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide afficial notice to the Health Services and Development Agency and all interested parties, in accordance with "I.C.A. Into provise imman more on the and services and to be services and Development Agency and all interested parties, in accordance with T.C.A. \$68-11-1001 of seq. and the Rules of the Health Services and Development Agency, that Implanted Turny Management. LLC owned by Roy Putrino with an awmership type of Single Member LLC and to be managed by Roy Putrino intends to file us application for a Certificate, of Novel for the establishment of a home care unpatiention and the initiation of home health services initiated to attenthed pump services. The estimated project cost is \$3,100. The agency will utilize one of intertheeling the services of the services in the services. The agency will utilize one of offices. Leasted at 200 Prawperity Place \$10.2, Knoxxille, TN 37923, As artivities the entire search. Services will be prevised within all 95 Tenuessee countries listed as follows: Audocson, Beford, Beston, Beteloe, Blount, Bradley, Campbell, Censen, Carroll, Carter, Chestham, Chester, Chelborn, Clay, Cocke, Coffee, Cruckett, Cumberland, Davidson, Deveatur, Dekolb, Dickson, Dyer, Flystit, Fentrets, Franklin, Gibson, Gile, Orainey, Grosse, Groudy, Handhen, Hazillon, Hangwood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Julireon, Knot, Lake, Lauderdskel, Lawrence, Lawis, Mozon, Molling, Methylin, Macco, Mariota, Marriell, Moury, Meigs, Moarne, Montgomery, Moore, Morgan, Obion, Overdon, Parry, Pickett, Polk, Pumark, Roe, Goult, Schotz, Servier, Schly, Smith, Stewart, Sullivan, Sumur. Tipon, Troundelle, Unicoi, Union, Van Buren, Warren, Warriell, Moury, Meigs, Moarne, Moren, Mentagomery, Moore, Morgan, Olion, Overdon, Purry, Pickett, Polk, Pumark, Roe, Lander, Marriell, Moury, Meigs, Moarne, Moren, Morgan, Olion, Overdon, Parry, Pickett, Polk, Pumark, Lucio, Lucio, Lundon, Purry, Pickett, Polk, Pumark, Roe, Roente, Robertson, Rutherford, Scott, Soulanchie, Se Soquatchic, Sevier, Shelby, Smith, Stevent Sullivan, Sumuer, Fipton, Froundale, Unicol Union, Van Buren, Warren, Washington, Wayne Weakloy, White, Williamson, Wilson, The rdiagnost date of filing the application is fully 7th, 2014. The contact person for this project is Melista Hess, Director of Nursing, who may be

7th, 2014. The contact person for this project is Medisas Hess, Director of Nursan, who may be reached at Intranscual Pump Monogeners, 200 Prosperity Place 2010. Ronoveille, TN 37523, telephonu (201) 475-9835.
Upon written request by interested partles, a local Fact-Finding public hearing shall be conducted. Written requests for hearing about does not be the 10th Sarvices and Development Agency. Andrew Jackson Bidding, 9th Floor, 592 Deaderick Sirvet, Nashville, Fannersee 37424. The published Letter of Intent most contain the following streemed pursant to 11CA, \$641-16079(1). (1), (A) Any health care institution withing to oppose a Certificate of Peed application usual file a written notice with the ffeaths Services and Development Agency on Jaterian (1) of 374 by health care institution with the testing of the propose of the regularity adopted the fields Services and Development Agency on Jaterian Withing to oppose the application to originally scheduled: and Development Agency are for prior to the consideration of the application by the Agency.

38301 Until: 1:00 p.m. 1:01 p. (Central Time) On: Westmentay, July 30, 2014.
Plan Rooms: West Tennessee Plans Room, Jackson, Tennessee: Reed Construction Data. Jackson, Tennossoe: Reed Construction Data.
Norceas, Georgia, Plan Deposit Amounts
5370,00. Designer: Bur & Cole Consulting
Engineers, Inc., 3483 Popular Avenue, Suite
200. Memphis, Tennessee 3811; Contact:
Stove Green. Phone: (901) 452-9676. PreBld Conference: At the facility, on July 16, 2014 at 1:00 p.m., Local Time (Central Time)

0101749629

Notice of Change in TennCare II Demonstration Amendment 23

The Commissioner of the Tennessee Department of Fi nance and Administration is providing official notifica tion, pursuant to 59 Fed. Reg. 49249, of intent to file an amendment to the TennCare II Demonstration. The demonstration amendment will be filed with the Centers for Medicare and Medicaid Services (CMS), a lederal agency located in Baltimore, Maryland, with a Regional Office

in Atlanta, Georgia, The State is required to meet certain advance notice obli cations whenever an amendment to the TennCare Dem constration is filed. This demonstration amend which will be known as "Amendment 23" is being filed

with a proposed effective date of August 1, 2014.
The subject of the amendment is prenatal care for preg nant women who have been deta nined Presum Eligible for TennCare. The state has always provided full TennCare benefits to these women, consistent with our managed care approach and the statement in our ennicare Demonstration Waiver that all services are considered programcy-related services.

CMS has advised the state that it needs to submit a way-er amondment to clarify that non-ambulatory services te.g., inpatient hospitalizations) can contisse to be cov-ered by Medicald for prepnant women during a period of Presemptive Eligibility. In order to keep in place our long-term practics of providing a full range of services to prepriant women during a period of Presumptive Eligi-hility, we are therefore requesting an amendment to the TenniCare Demonstration that would provide the expenditure authority to continue providing these services. This amendment will not result to any changes in exper

Copies of this notice will be available in each county of lice of the Tennessae Department of Health, and on the TennCare website located online at http://www.tn.gov/ tenncare/. Written comments may be submitted by email to Sucle.Baird@tn.gov or may be mailed to the Darin Gordon, Director, Bureau of TermCare, 310 Gree Circle Road, Nashville, Tennessee 37243. Persons wish ing to review copies of written comments received may submit their requests to the same email another physical

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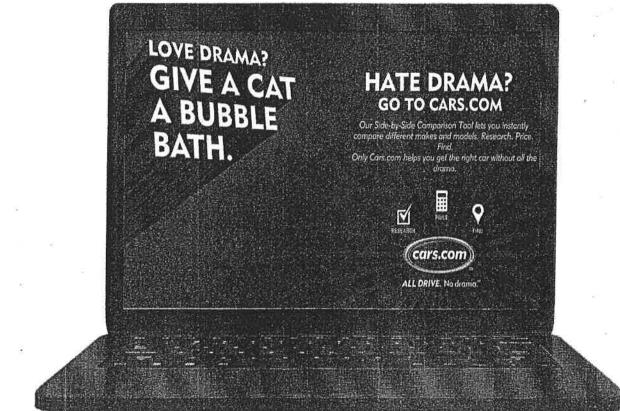
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AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Johnson City Press with circulation and coverage within the following counties: Washington, Sullivan, Carter, Greene, Unicoi, Hawkins, and Johnson (7 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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activation of the moor enter-seation, step by the Central 1320. You can also apply for Tary route state before or to have your application on file by going to: Ethiopinas dipotest con-tact on server application as below of page.

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AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Kingsport Times-News with circulation and coverage within the following counties: Washington, Sullivan, Hawkins, Carter, Greene, and Johnson (6 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensiky, Agounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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Transportation

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Announcements

- Hotlines
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 Special Notices



- 100. Professional Services 110. Home Improvement 111. Lawn Service 112. Polariting & Pumpering 120. Implement Repairs 130. Paving 131. Concrete & Rock Work. 140. Heat, All Pack 141. Electrical Repair

- 180, Generof Er 190, Profession 196, Bullding & 200, Medicatto 210, Soles, Age 220, Industriol, 230, Office, Die 240, Dornestic, 250, Resiguean 260, Part-Time 270, Joha Wash 290, Transported 295, Employmen 296, Job Prepar General Employment Professional Building & Remodeling Medical/Denial Sales, Agentales Industrial, Trades Office, Chelcal Domestic, Child Care Restourants Part-Time Joba Wants Tramportation Employment Agencies



300-310

300. Musical 310. Educational



Farming 320-370

320. Farm Equipment 330. Food 340. Numeries 350. Livestock 360. Poutry 370. Feed, Seed, Plants



- 380. Appliance
 380. Machinery, Tools
 400. Pets. Supplies
 410. Garage, Rummage Sa
 420. Miscellaneous
 421. Clothing
 430. Household & Antiques
 431. Furnishings

680, Mobile Home Sites-Sale or Rent 690, Wanted to Rent 700, Business Property for Rent



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The the 5th day of June 2014

Wanda Ratey Estate of DWIGHT T, KILBY Cook Lews.

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M THE CHANCERY COURTY AT DESCRIVEN COURTY AT BLOUNTVALE, TENNESSEE NOTICE TO CREDITORS

WILLIAM EDWARD FINNEY. JR. DECEASED

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or claimed:

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(E) Sixty (00) days from the data the conditor received an actual copy of the Notice to Crystolers of the section remarked his copy of the Pictors was their savely (60) days provide the data of the their some their savely (60) days provide their some the data of their some their savely (60) days provided their savely (60) days provided their savely (60) days provided their savely as their savely as their savely as their savely as their savely days of their savely day

(2) Twelve (12) months from the decedent's date of death. All person indicted in the above extate must come for ward and make proper safe-ment with the undersigned at once. This the 10th day of June 2014

> Wmam D. Friving. Attendey for the Estate Annies Holographics North Control

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We offer a competitive bornell package select includes Madical, Dentel, Varon Insurance STDATD Escution PTO Plan

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TimesNews

MITIAL RESOLUTION AUTHORIZAND THE BRUANCS OF GENERAL OBLIGATION BONDS BY THE TOWN OF BURGONSYALE, TENNESSEE IN A PAR AUGUST NOT TO EXCEED 885.000 TO FRANCE SEWER SYSTEM AN PROVENCESTS AND EXTENSIONS AND RELATED COSTS.



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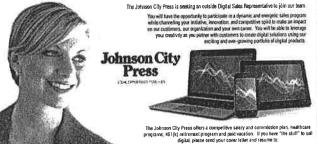
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Bret Jacomet, Vice President of Digital biacomet@thenetmg.com

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Knoxville News Sentinel with circulation and coverage within the following counties: Grainger, Knox, Sevier, Union, Blount, Jefferson, Cumberland, Scott, Campbell, Claiborne, Anderson, Morgan, Roane, Loudon, Monroe, McMinn, and Cocke (17 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

NON-RESIDENT MODICE

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This the 38th day of JUNE, 2814
Estate of MARTHA LYNN CASH
PERSONAL REPRESENTATIVE(S):
Kell C, Kewn Elecution
200 Bettypnob Lyter
Kropsville, 71 27722

NOTIFICATION OF

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INTERNI TO APPLY FOR A
CERTIFICATE OF NEED
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NOTICE TO CREDITORS ISSEPH LEE DUGGAN

DOCKET NUMBER 7984-3

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PERSONAL REPRESENTATIVE(3)
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NOTICE TO CREDITORS

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Con Tubes, Flat Bare and
Angles Experienced Metal Star Framers and Deposit Hangers needed. Must have depletable inne-portation. Thi Disp Fine Wondlate. I minimized please has 865-655 Post Monday - Priday between 8 and 4. Securities Stutico & SIFS Application Needed Minimum 2 yes exc. Willing as well as in 100 to. Once street will Cast 423-523-7348

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Newspaper routes available now in the Lenoir City Area.

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- The Bon Atchley TN State Veterans Home in Knoxville is seeking candidates for the following positions:

 * RN Supervisor 11pm-7am Only

 * Certified Nursing Assistants

 * Activities Assistants Full-time & Part-time

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Successful candidates will be highly motivated, dedicated and well trained.

We offer a competitive salary and benefits package, including participation in the state retirement programs; and a fantastic work environment and excellent career advancement opportunities.

Previous experience in a Long Term Healthcare setting preferred. APPLY IN PERSON AT;

APPLY IN PERSON A1;
Ben Atchley TN State Veterans Home
9910 Coward Mill Road
Knoxville, TN 37931
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July 30, 2014

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July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Buffalo River Review* with circulation and coverage within the following counties: Hickman, Perry, and Wayne (3 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

THE "ULTIMATE" ESSUPPLEMENTAL #1 PUBLIC NOTIC July 30, 2014

Legal Notices can be viewed at our website: www.turstancemanns.com under the Public Notices tab. Other TPA newspapers poeting legal notices online may be found. by visiting: www.tnoublicnotice.com (a division of tripress.com)

SUBSTITUTE TRUSTEE'S SALE

SUBSTITUTE TRUSTEE'S SALE
Sale at polici auction will
be on July 22, 2014 at 10:00 AM
local time, at the front door, Peny
County Gourstone, 121 East Main
Street, Linden, Tennensee pursuant
to Dead of Trust ascended by Kellie
D. Helme, an unmartied woman, to
Annold M. Weiss, Esq., Trustee, as
trustee for Weile Fargo Bark, N.A.
on February 20, 2007 at Book 94,
Rapa 35, Insurent No. 07027098; Page 35, Instrument No. 07027068; conducted by Shapiro & Kirsch, LLP having been appointed Substitute or Successor Trustee, all of record in the Perry County Register's Office Default has occurred in the performance of the covenants, terms, and conditions of said Dead of Trust and the entire indebtedness en declared due and pavable

has been declared due and payable,
Party Entitled to Enforce the
Debt HSBC Bank USA, National
Association as Trustee for Wells
Fargo Home Equity Asset-Backed
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prior deed relievences subjected sale is subject to confirmation by the property to contain 3.1 licemia. However the property conveyed to Kalife D. Helms an unumaried woman, by deed from Frank Varney and wife collector. This office may be a debt from Frank Varney and wife collector. This may be an altempt 20,2007, of record in Book D-3, obtained may be used for that 20,2007, of record in Book D-3, Page 737. Register's Office for Perry County, Tennessee. Subject to all elemenants and conditions, and other matters of record, including all liems all out on any applicable plat of precord.

net out on any appacasie part of record. Street Address: 8063 Highway 412 East, Linden, Tennessen 37096 Parcel Number: 081-113

Јов LISTINGS THIS WEEK

The Tennessee Career Center has the following job orders for this week: CERTIFIED NURSING ASST. Linou, Paya DOE

UC, PRACTICAL NURSE CONTENNUE, Per 19 DOE

addition to the above listings, as website John4TN gov has over 5 other jobs located within fifty

or mire information about those and other jab Hittings, call the Tentesseen Exercit Center for the Tentesseen Exercit Center areas by the Canac Center at 11.7 Feature St., Lieuten, 19. or context your marries.

woman
Other interested parties: North
Star Capital Acquisition LLC o'o
Buffaloe & Associates
The atreet address of the

above described property is believed to be 8063 Highway 412 East, Linden, Tennessee 37096, but such address is not part of the

but such address is not part of the legal description of the property cold herein and in the event of any discrepancy, the legal description herein shall control.

SALE IS SUBJECT TO TEMANT(IS) RIGHTS IN POSSESSION.

This nade is subject to all matters shown on any applicable recorded plat any unpel dures; and any restrictive coverants, assements, or seducat kines that may be applicable; any situation right of medemption of any governmental redemption of any governmental agency, state or lederal; any prior tiens or encumbrances as well as

collector. This may be a a debt collector. This may be an allempt to collect a debt and any information obtained may be used for that purpose, Fluit Publication Date; Jun 25, 2014

B 779
SUBSTMUTE TRUSTEPS SALE
Sale al public auction with be
on August 7, 2014 at 12:00PM
local time, at the forul door, Perry
County Courthouse, 121 East
Main Street, Linden, Tennessee,
persurant to Deed of Trust seconds
by John Cappa, a married person, to
Larry N. Westbrock, Eary, Trustee,
or Jane 3, 2001 at Book 73, Page
587; all of moord in five Perry County
Register's Office,
Parry entitled to enforce
security interest Secretary of
Veterans Affairs of Washington,
D.C., its successors and assigned
The following real state
located in Perry County, Tennessee,
with the significant forum of the forum of the Office,
The following real state
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with the soft of the Director. Any Interested bidder may expected
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The following real state
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The following real state
located in Perry County, Fornessee,
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1, 37:096, (931) 599-2102. The
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Perry County Bondor of Educat

Veterans Affaire of Washington, O.G., its successors and assigning The following real estate located in Perry County, Terroressee, will be said be highest call bloder subject to all unpast traves, prior lens and encurbances of record: Described property located in Perry County, Terroressee, and being more particularly described in Book 78, Page 800; her property of the prior property of the prior property of the prior prior the prior prio

Schnelder has freight to move right now! and intermodal opportuniti Up to \$5,000 sign-on burger may apply (depending on transmit) Copyright of the Add system of the parties of Copyright South (Add system of the parties

above described property is believed to be Route 1 Box 270, Lobelville, Tennessee 37097, but such address is not part of the

SUCH sodress is not part of the begal description of the property soot herebs and is the owned of any descripancy, the legal description reterenced herein shall control.

SALE IS SUBJECT TO ONE YEAR RIGHT OF REDEMPTION HELD BY U.S. SMALL BUSINESS ADMINISTRATION BY REASON OF THE DEED OF TRUST OF RECORD AT 1800K 104, PAGE 183, IN THE REGISTER'S OFFICE OF PERRY COUNTY, TENNESSEE agincy, state or source.

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Business and in any matter that an accumate of the promises might disclose. In addition, the blowing the above-reterenced property. North Sater Capital Acquisition LLC do Buffalos & Associates

Auf right of equity of addengtion, and the state of the stat

Substituta Trustee
Lew Office of
Shapin & Kisseh, LUP,
555 Perkins Road Extended,
Second Roor
Memphis, TN 39117
Phone (801)767-5596
Fax (901)761-5590
www.kisschaftsmenra.com
File No. 14-59216
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nt Publication Date; Jun 25, 2014
Scharthalt Trustee
Law Office of Shaphor & Kirach, Lup
Scharthalt Trustee
Law Office of Shaphor & Kirach,
Lup
S55 Perthine Road Extrands,
Second Floor
Memphis, TN 33117
Phone (601)787-5569
Fax (901)787-5590
Law Mathematicans area.
Law Office of Shaphor & Carlot Shaphor & Carlot

Phone (6/1)787-5569 2014: Chamicals & Cleaning Supplies; Detwork Minchaltemany actors File No. 11-014264 B 7/8 Meal, Esh, poultry, and meat alternative;

Perry County Board of Education reserves the right to accept or reject anytor at bids.

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B 7/9

NOTICE TO CREDITORS Estate of NANNIE GERTRUDE GORDON, Late of PERRY County,

Notice is hereby gleen flash on the 24th day of June, 2014, Labera Testamentary in respect to the Estate of NANNIE CENTRIDIC GOPPION. Occased, who deed April 23, 2014, were issued to the undersigned by the Chancery Court of Penry County, Tellemente.

All persons, resident and non-resident, having claims, maittend or unmattend against the Estate are required on file the same in triplicate with the Clerk of the above named Court on or below the earlier of Notice is hereby given that on

in the Register's Office of Penry
County, Tennissee
Secondary Property', Address:
John W. Capps aka John
Capps:
Office Interested parties: U.S.
Small Business Administration
The steet address of the
rev described property' is
dails of the first publication (or prosting, as the case may be) of this notice in creditions at least sold; (50) days before the dails that is four (4) months from the dails of the first publication (or prosting); or prosting; or

one by (so a postation (or (B) Solty (60) days from the date the creditor received an actual copy of the notice to creditors if the creditor received the copy of the notice less than sixty (60) days prior to the date that is four (4) months from the date of the first publication as described

in (1) (A); or (2) Twelve (12) months from secodent's data of death. This the 24° day of June, 2014.

2014.

Graham Fisher, Executor
Estate of NANNE GEHTRUDE
GORDON
Charlene Brown,
Perry County Clerk & Master
Jarrod P. Huddleston, Attorney
DuBols & Dubols, P.C.
810 South Garden Street
P.O. Don 313 P.O. Box 339 Columbia, TN 38402-0339

NOTIFICATION OF INTENT TO APPLY
FOR A CERTIFICATION OF THE PROPERTY OF THE PRO NOTIFICATION OF INTERT

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Proposea Pe	rry Co	unty b	uagei
For Fiscal Year	Ending	June 30,	2015
GENERAL FUND*	ACTUAL 2012-2013	ESTIMATED 2013-2014	

ı		ACTUAL	ESTIMATED	ESTIMATED
ı	GENERAL FUND*	2012-2013	2013-2014	2014-2015
П	Estimated Revenues			
ı	& Other Sources	** ***	*****	42 274 7/1
1	Local Taxes	\$1,972,692 \$668,756	\$2,164,952 \$1,010,583	\$2,274,761 \$1,374,251
1	State of Tennessee Federal Government	\$54,538	\$16,856	\$30,000
ı	Other Sources	\$2,456,971	\$1,577,712	\$855,416
ı	Total Estimated Revenues and Other Sources	\$5,152,967	\$4,770,103	\$4,564,428
1	Estimated Expenditures	1		
1	& Other Uses			
П	Salaries	\$2,697,451	\$2,040,736	\$2,083,155
П	Other Cost	\$2,680,354	\$2,654,497	\$2,481,273
1	Total Estimated Expenditures		44 605 830	C4 544 430
П	and Other Uses	\$5,377,805	\$4,695,233	\$4,564,428
П	Estimated Beginning Fund	\$307,476	\$230,987	\$305,857
П	Balance - July 1 Estimated Ending Fund	\$307,476	\$230,707	\$505,057
1	Balance - June 30	\$230,987	\$305,857	\$305,857
1	Employee Positions	118	108	108
П	CONTRACTOR		100	
ľ	HIGHWAY/PUBLIC WORKS FU Estimated Revenues	ND		
П	& Other Sources			
П	Local Taxes	\$45,000		\$55,099
Л	State of Tennessee	\$2,417,742	\$1,989,692	\$1,796,417
П	Other Sources	(\$412,462)	(\$153,956)	\$15,000
н	Total Estimated Revenues	en 050 ano	#1 000 E16	\$1,866,516
П	and Other Sources	\$2,050,280	\$1,882,516	\$1,000,510
П	Estimated Expenditures			
П	& Other Uses	4500 450	\$578,545	\$583,000
1	Salaries Other Cost	\$500,478 \$758,077	\$2,100,393	\$2,095,938
1	Total Estimated Expenditures	\$7.50,077	\$2,100,375	\$2,075,750
١	and Other Uses	\$1,258,555	\$2,678,938	\$2,678,938
1	Estimated Beginning Fund	\$3,605,037	\$4,008,193	\$3,805,000
1	Balance - July 1 Estimated Ending Fund	\$3,003,037	34,000,173	\$3,503,000
١	Balance - June 30	\$4,008,193	\$3,211,771	\$3,008,578
١	Employee Positions	16	16	16
1		****		
١	GENERAL PURPOSE SCHOOL Estimated Revenues	PUNIZ		
1	& Other Sources	e1 E2/ 005	#1 EE4 FOE	\$1,629,405
1	Local Taxes State of Tennessee	\$1,526,907 \$6,636,230		\$6,673,505
1	Other Sources	\$2,051,686		
1	Total Estimated Revenues	\$2,002,000	44,04,04	
Н	and Other Sources	\$10,214,823	\$10,384,839	\$10,013,399
1	Estimated Expenditures			
1	& Other Uses			
1	Salaries	\$6,681,392		\$6,920,377
1	Other Cost	\$3,502,287	\$4,050,084	\$3,514,586
ı	Total Estimated Expenditures and Other Uses	\$10,183,679	\$10,829,005	\$10,434,963
	Estimated Beginning Fund			
1	Balance - July 1	\$758,877	\$790,021	\$345,855
1	Estimated Ending Fund			*
1	Balance - June 30	\$790,021		\$345,855
1	Employee Positions	225	225	225
П	DEBT SERVICE FUND			
1	Estimated Revenues			
1	& Other Sources			
1	Local Taxes	\$802,800		\$547,429
1	Other Sources	\$1,219,607	\$660,269	\$555,200
	Total Estimated Revenues and Other Sources	\$2,022,407	\$1,209,781	\$1,102,629
1		42,024,407	41,202,701	2.,,027
1	Estimated Expenditures			
1	& Other Uses Debt Service Cost	\$944,314	\$1,600,155	\$1,189,500
	Total Estimated Expenditures	477774	,000,100	
	and Other Uses	\$944,314	\$1,600,155	\$1,189,500

\$1,920,850

\$1.833.979

\$2,311,224

\$1,920,850

\$2,063,199 \$2,311,224

Estimated Beginning Fund

Balance - July 1 Estimated Ending Fund Balance - June 30

July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the McMinnville Southern Standard with circulation and coverage within the following counties: Warren, DeKalb, Cannon, and Van Buren (4 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

30,

4-C - Southern Standard, McMinnville, Tenn., Wednesday, July 2, 2014

A STEPA Cisymand Viscon conveyance (deed of trust) to which reference is here, surject with coloring construction industry (or similar industry)

Manchester, TN 37349 Send resumes to P.O. Box 1820

at the front door old the C courthouse in Warren R County, Tennessee, offer di for sale and sell to the highest and best bidder time position without the constant great attitude and sense of loyalty, able to work well with others, and Are you a people-person with a unafraid of hard work in a fullsupervision of management?

me as trustee, I will on Thursday the 17th day of July, 2014, at 12:00 o'ctock

a hearing on the 4th day of August 2014 at 9300 a.m. in the General Sessions Court room in McMunville, Tennessee. This the 1th day of June, 2014.

emadette Morris, Clerk 7419 W4t7-9

> If you can answer YES to these questions, our sales team needs you!!!

for cash, and in bar of the equity of redemption, the lollowing described trect of land: of land: 018 MAPPARCEL: 112-055.00

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473-2191 WORK

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NOTIFICATION OF INTENT TO

APPLY FOR A CERTIFICATE OF NEED work unspecified hours. No benefits cations will be accepted at Workforce Solutions, 310 N. Chancery Street, McMinnville, TN until 12:00 PM on and must be willing to complete required training. All applicants will be subject to a pre-employment drug Monday, July 21st, 2014. Applicants or equivalent; basic computer skills; test and complete background check cepting applications for a part-time, as-needed Judicial Commissioner to must posses a High School Diploma are available with this position. Appli-Warren County,

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Garage Sale 545 Ridgecrest Drive Thursday, 7/3/14, 7 a.m.-4 p.m. Friday & Salurday, 7/4&7/5, 7e.m.-2p.m.

nnon, Kiiux, Lake, Lauderdale, Lawrence, Lewis, Icolii, Loudon, McMinn, McNairy, Macon, Madisou, roll, Carter, Chesuhau, Chester, Chaborne, Clay, Cocke, Nee, Cruckett, Cumberland, Davidson, Decalur, Dehalb inger. Greene, Grunty, Humblen, Hamilton, Hausock, Gron, Dyer, Fayette, Funtress, Franklin, Glbson, Giles ian, Hardin, Hawkins, Haywood, Hend IMMEDIATE FULL-TIME

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July 30, 2014 9 :54 am

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July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Commercial Appeal with circulation and coverage within the following counties: Shelby, Crockett, Tipton, Dyer, Hardeman, Fayette, Haywood, Lauderdale, McNairy, Chester, Henderson, Carroll, Madison, Hardin, Gibson, and Obion (16 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Wensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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Apartments (unfurnished) Area Map SUPPLEMENTAL #1

July 30, 2014 9 :54 am

July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Murfreesboro Daily News Journal with circulation and coverage within the following counties: Bedford, Williamson, Rutherford, Wilson, Cannon, Marshall, and Lincoln (7 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Appointing Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public



July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Paris Post Intelligencer* with circulation and coverage within the following counties: Benton, Carroll, Henry, and Weakley (4 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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for the purpose of receiving the proposed budget and discussion of budget for Fiscal Year 2014-2015.

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PREVENTION COALITION

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APPLY FOR A CERTIFICATE OF NEED NUTIFICATION OF INTENT TO

HENRY COUNTY

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OJN FARMS

tion strategies, implementing county wide impact activities, and recruitment of additional partners.

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The Dueste or Nasangag who may be acid-date all introduced
Thy 2023, telephone, (2011) 475-8955.

Coalition responsibilities will include organizing coalition meetings, researching effective preven-

prescription drugs in Henry County.

hen please email

Paris, TN 38242 Or Mail: HR Department

No phone calls please. P.O. Box 30

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COORDINATOR

inneal is unrathesal jointy cavitee. The estimated processes is \$8,100. The agency will unlare one offices heared in 200 Prosperity Place a 102. Knoaville, TN 17923, so eavice the entire state. Services will be provided within all

PROGRAM

ACCOUNTING ASSISTANT ACCOUNTS PAYABLE/

> The Coalition is comprised of community partners age and binge drinking, and reducing under age tabacco use in our youth and non-medical use of

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Social Work, Psychology or related field.

Bachelor's degree in the field of

interested in preventing and reducing under

billing for misc parts usage, its: Excellent Microsoft Excel skills and 3+ years ponsibilities: Process payables for three separate legal es. Review all invoices for appropriate documentation prior to payment. Enter inter-company billing

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> have the ability to attend out of town trainings Driver's License and reliable transportation and

Please submit resume, letter of interest, and Fax: 731-642-1010 Attn: HR Dept. Email: resumes@careyinc.org

Upon written request by interested parties, a local Fact-Fadding upblik besting shall be conducted. Writen requests for heaving should be seen to: Health Services and Development, a speers, Andrew Acklean, Buldings, 916. Floor, 322 Desferted. Street, Nuchrifte, Trensacre-977243. The published Letter of Ignest must contain the

following spirement parsunat to T.C.A. § 68-11-1607(e) (1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice

position(s) of interest to:

motivated and must possess a valid Tennessee

Applicants should be self-directed and self-

ent where contributions are recognized and where team rembers hold each other secondable for meeting deadlines, opportunity to partiquate in a system conversion towards ai-end 2014. Sereids include; health insurance, 401k and fhat we offer, A fast paced, comfurtable work environ-

nown accounting system and will appreciate a sense implishment as we position Tosh Farms for the future. If you are motivated by a challenge, want to learn a new

For established

On

Base salary & benefits required with strong work ethic & desire to provide outstanding plus commission. Sales experience customer service.

Senior Officer

P.O Box 310-110 Paris, TN 38242

July 30, 2014 9 :54 am

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July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in *The Tennessean* with circulation and coverage within the following counties: Robertson, Davidson, DeKalb, Williamson, Cheatham, Cannon, Bedford, Sumner, Hickman, Dickson, Smith, Rutherford, Montgomery, Stewart, Houston, Trousdale, Humphreys, Macon, Warren, Maury, Wilson, Lawrence, Lewis, Putman, Jackson, Giles, Marshall, Lincoln, and Moore (29 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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Call Shaddy 615-815-9190

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July 30, 2014

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http://lin.gov/grocestart-/pun/tye/t/freef.shreef. Progressive roay request a copy of the RFF by creationing Ma. Tamony Michibins, RFF Condi-ratio, at (615) 233-7819. Propositio are experted to be sheet in Rey 2014. In principle.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED This is no presents effect nature to the Health Services and Development Agency and all seasoning panies, as accordance with LCA.

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Dogs

July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the Rogersville Review with circulation and coverage within the following counties: Hawkins, Sullivan, Greene, Hancock, Grainger, and Hamblen (6 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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Monday - Priday 8 a.n. - 5 p.m.

Garage / Yard Sales
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from the

(2) Twelve (12) months fro decedent's date of death,

Holly H. Jaynes Clerk and Master 2x 06/25;07/02/2014

Yard S. July 3" - 57 720 Tuggle Till Rd. Og of

3 SERVICAS

Public Notices Public Notices

Public Notices

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

WHERSEX, Lewis I. Beasto III., Jennise I., Microwan and Eugenia B. Biustio accused a Deed of Treat to Branch Burdony and Tract Company, Landon and BB & I. Collaberal Service Corporation, Tracebol, which was dated Apail Ez. 2006 alm recorded on May 5, 2006, Blook 802, Page 883, Heavilhar County, Trientesee Register of Deeds. The is to provide english oracis to the Table Sevicis and Development Against and the is to provide english oracis on the Table Sevicis and Development Against with the Hulls of the Hulls

NOW, THERETORE, notice is hareby given that the entire indichtedness has been decleared the set opposed as approvious read and of Titlats by the Hold-life and the set as agent for the undersigned, Brock & Scott, PLIC, Substitute Titlates, by whice of the power and authority vested it is, and in on by it, SOM, at a 100MM at the usual and customary bosision at the Hewkins County Court. Mouse, Roberselle, Eremasses, proceed to sell at public outcry to the highest and best bidder for ceah, the following described property shaated in Hawkins County, Terresses, to will.

Shutte in the Second Cwil District of Hewkins County, Tennessee, and being more particularly described as follows:

CHELAQUE HOMEOWNERS AS IN RE: ESTATE OF JOHN P. COX, SOC.

SAMUEL J. MITCHELL and AUDRA J. KIDD

VS. NO. 2013-PR-178

This 17" day of June, 2014.

April Stovati Administratrix Allen J Coup Attorney

All right and equity of redemption, statumy or otherwise, homesteed, and dow-er are expressed without in said Deed of Trust, and the libe is believed to be good, but for unfamigned will sell and convey row as Substitute Trates. The right is reserved to adjourn the day of the sale to another day, time, and place orders without thather outsidedon, upon parroundment at the sine and place for the sele set forth above.

This office is attempting to collect a debt. Any information obtained will be used for that purpose.

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TAX PARCEL ID: 07-012G-G-012B-011.00 DEED BOOK 213, PAGE 255

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Of Interest NOTICE TO CREDITORS Public Notices

No. 37CH1-2014-PR-112

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All persons indebted to the above Es-tate must come forward and make proper settlement with the under-signed at once.

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3 Family Yard Sale: Wed.-Frl. 8-4 at 1504 Hwy. 70 N. (below Rock Hith Grocery) Lots of clothing and misc. household items.

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NOTICE TO CREDITORS

No. 37CH1-2014-PR-107

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9

(A) Four (4) months from the

July 30, 2014 9 :54 am

AFFIDAVIT

July 29th, 2014

Implanted Pump Management LLC 200 Prosperity Place #102 Knoxville, TN 37923

Gentlemen:

The enclosed itemized statement is for publication of Notification of Intent to Apply For a Certificate of Need in the *Union City Daily Messenger* with circulation and coverage within the following counties: Obion, Lake, and Weakley (3 counties total).

This publication took place on July 2nd, 2014.

I, Kathy Hensley, Accounting Services Representative for Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Ninth day of July 2014

Kathy Hensley, Accounting Services Representative

Sworn before me this 29th day of July 2014

Earl Goodman, Notary Public

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The Messenger, Union City Tennessee, Wednesday, July 2, 2014

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August 18, 2014 12:30 pm



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364/Fax:615/532-9940

August 14, 2014

Melissa Hess, RN
Director of Nursing
Implanted Pump Management
200 Prosperity Place #102
Knoxville, TN 37923

RE:

Certificate of Need Application CN1407-027

Implanted Pump Management

Dear Ms. Hess,

This will acknowledge our July 28, 2014 receipt of your supplemental response pertaining to your application for a Certificate of Need for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services to patients residing in all 95 Tennessee counties from its parent office located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932.

The application is incomplete. A number of items also need additional discussion and /or clarification. Please review the items and respond as soon as possible. Should you need technical assistance regarding the format of the application, please contact me by e-mail or phone at extension 615-770-0492.

Towards the end of this letter you will find information regarding "deemed complete" or "deemed incomplete" status of an application and a "deemed void" date. If this application is not complete prior to that date, it will be deemed void. In order to help expedite the review process, please resubmit all required information in the format described and respond to our initial questions in triplicate, with affidavit by 4:00 p.m. July 31, 2014. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section A, Applicant Profile, Item 4

A reply to this question was not included in the 7/28/14 supplemental response. The question is repeated as follows:

The owner's formation as a New Jersey limited liability corporation with one member is noted. Is the applicant registered to do business in Tennessee? If so,

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please provide documentation of the owner's registration with the Tennessee Secretary of State.

Implanted Pump Management LLC registered to do business in Tennessee on October 24th, 2013 (see Attachment 1.Section A.Item 4).

2. Section A, Item 6

A reply to this question was not included with the applicant's 7/28/14 supplemental response. The question is repeated as follows:

The office service agreement for the parent office of the proposed HHA at 200 Prosperity Place in Knoxville, TN indicates a rate of \$325 per month from December 2013 through January 1, 2015. Is this an office rental agreement similar to the usual and customary commercial office rentals in the Knoxville area? Please identify the size, in square feet, of the office, the number of occupants that will use the office and compare the rental rate to other similar professional office space in Knoxville.

Since licensure may not occur at the earliest prior to January 1, 2015, it appears that the rental arrangement will expire at the start of the applicant's first full year of operations. Please provide an addendum with extension to the rental agreement.

Our office rental and rate is similar to rental rates for offices of the same size and amenities in the Knoxville area, although we have chosen to utilize the most cost-effective. Located at 200 Prosperity Place in Knoxville, our office has a total area of 80 square feet with dimensions of 8 feet by 10 feet and our rent costs \$325 per month. We considered several similar offices in the area: a 10' by 10' cottage alongside an engineering firm, costing \$350 per month on South Peters Road (includes utilities); a 11' by 12' office within an executive suite building with 24/7 access costing \$400 per month, rented through Southland Realtors (contact: Larry Anderson, landerson@southlandrealtors.com); and a 10' by 13.5' office within an executive building costing \$370 per month, rented by the company Executive Suites (contact number: 865-694-0840). (Please refer to Attachment 2.Section A.Item 6.Alternate Offices for information regarding the aforementioned rentals.) The locations within the office buildings included amenities similar to those we receive at our current location, also at no extra charge. We chose to rent the most affordable location that included these amenities.

As our current rental agreement ends on January 31st of 2015, we have added an addendum to this agreement in order to extend it through December 31st of 2015 (see Attachment 2.Section A. Item 6.Rental Agreement for both our current agreement and the addendum). Our monthly rate will increase from \$325 to \$349 per month during the time specified by our addendum.

The only occupant that will utilize this office will be our RN Administrator. No patients or caregivers will ever be seen at this location, as all services are to be rendered in the home.

3. Section A, Applicant Profile, Item 13

Melissa Hess August 14, 2014 Page 3 August 18, 2014 12:30 pm

A reply to this question was not included in the applicant's 7/28/14 supplemental response. The question is repeated as follows:

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Why has the applicant decided not to provide intrathecal home infusion services to TennCare/Medicare enrollees? Is the service generally a covered service under these payor groups? Please discuss.

Please clarify if TennCare and/or Medicare enrollees will be provided infusion services as out-of-network or under some other arrangement.

If the applicant does not plan to provide intrathecal home infusion nursing services to TennCare/Medicare enrollees, where would enrollees be referred for those services? If a home health provider is not located, would an enrollee be required to travel on-site for infusion services? Please be specific.

In other parts of the application, the applicant states that home health patients in Tennessee have limited, if any, access to intrathecal home infusion services. Do these difficulties only apply to non-TennCare and Medicare patients? Please clarify how a non-homebound patient who needed intrathecal infusion services would receive those services.

Implanted Pump Management (IPM) will not be providing intrathecal home infusion services to TennCare/Medicare enrollees as this proposed service is not a Medicare covered benefit. The proposed therapy is excluded from traditional Medicare guidelines. The proposed services therefore will not be accessible to TennCare and or Medicare enrollees.

As IPM does not intend to offer the proposed services to Tenncare/Medicare enrollees, those individuals will continue therapy by utilizing the individual ordering physicians office for refilling and intrathecal pump management.

At this point, with limited or no intrathecal home infusion service providers in the state of Tennessee, all patients, regardless of insurance, face a lack of access to these services. In regards to individual patients' covered benefits, the proposed services would only be covered with a plan that includes a home infusion service benefit. Medicare/TennCare plans currently do not offer coverage for the proposed home infusion services.

4. Section B, Project Description, Item I

The responses to Items 5.A - 5.L in the 7/28/14 supplemental response are noted. Additional clarification is requested as follows:

A. With respect to patient services, please describe how pump function is checked using telemetry readings in accordance with practice guidelines.

The pumps software features a number of system and therapy monitors. These are classified into critical and non-critical events (ie. empty reservoir, low reservoir, pump stopped, motor stall occurred, pump stopped for longer than 48 hours, and warning that pump will stop in 90 days). A trained RN checks the pump function by interrogating the pump with the programmer. The source of the alarm is included in the telemetry report. In addition, with every

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interrogation the RN checks accuracy of type of, dosing, and delivery of medication that is also displayed on the telemetry report.

B. With respect to the responsibilities of the patient's physician, please clarify how IPM proposes to create awareness of its services such that it receives physician orders for the care of their patients in the home setting. Please describe what is meant by a therapeutic arrangement with the ordering MD (item 5.F).

A therapeutic relationship is also called a "helping alliance." It refers to the relationship between a healthcare professional and a client. IPM simulates a therapeutic relationship with the ordering physicians with whom they work by increasing the exchange of information, knowledge, and clinical assessments derived from homecare visits. This model creates a "helping alliance" that facilitates clinical outcomes and patient satisfaction with the proposed therapy.

The IPM RN only acts on direct orders from the managing MD. The IPM RN will obtain a signed order from the physician for every pump refill or any dose adjustments needed, and will provide the pertinent information to the MD via phone, fax, email, or in-person to make an informed decision. All forms of communication with the MD will follow the mandated HIPAA guidelines by the state of Tennessee to ensure patient confidentiality and safety. The ultimate goal of the therapeutic relationship is to achieve optimal patient outcomes.

C. Please describe the proposed HHA's plans to contract with infusion pharmacies for intrathecal medications. This should address the nature and scope of services, coverage areas in TN, methods for distribution of product, etc. In your response, please identify the names of the pharmacies, addresses, license status and accreditations, if any.

IPM intends to apprehend a contracting arrangement with a 2-3 accredited pharmacies in order to provide the highest quality infusion services to Tennessee patients. IPM will forward the signed order by the MD to the pharmacy and the pharmacy will bill for its own services.

We are currently planning to contract with Intrathecal Compounding Specialists (ICS) at 206-A Jacob's Run, Scott, LA 70583. ICS is accredited by the Pharmacy Compounding Accreditation Board (PCAB) and currently holds valid licensure within the state of Tennessee (see Attachment 4.Section B.Project Description.Item 1.Pharmacy License). Please see attached contract draft for pharmacy services (Attachment 4.Section B.Project Description.Item 1.Pharmacy Contract) and letter from Mr. Stuart Burgess R.Ph., Director of Pharmacy, attesting to ICS's interest in contracting for pharmacy services in Tennessee (Attachment 4.Section B.Project Description.Item 1.Pharmacy Letter).

D. Elsewhere in the supplemental response, it appears that the applicant has identified 1 of 157 licensed HHAs that provides an intrathecal homecare management service. Who is the HHA, where is it located (home and branch offices), what is its licensed service area (names of counties

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authorized in license), and what was the HHA's utilization reported to the Tennessee Department of Health for the past 3 years (as reported in its Joint Annual Report)?

Camellia Home Health of East Tennessee, LLC is located at 1700 Liberty Street NW, Knoxville, TN 37921. This agency holds 3 home health licenses in MS and one home health license each in TN, LA, and GA according to their website (www.camellia.com). Within Tennessee, Camellia is licensed to provide home health services within the following 28 counties according to their licensure information as listed on the Tennessee Department of Health Anderson, Blount, Bradley, Campbell, website, http://health.state.tn.us: Claiborne, Cocke, Cumberland, Grainger, Grundy, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Knox, Loudon, Marion, McMinn, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, Union (see Attachment 4.Section B.Project Description. Item ID. Camellia License Info for a printout of Camellia's licensure information and Attachment 4.Section B.Project Description.Item ID.Camellia County Coverage for a map from Camellia's website).

Camellia's report to the Tennessee Department of Health for the year 2013 reflected the provision of the following services: Home Health Aide Services, Medical Social Services, Occupational Therapy, Physical Therapy, Skilled Nursing Care, and Speech Therapy (see Attachment 4.Section B.Project Description.Item ID.Camellia Services for a listing of the broad range of services provided, taken from Camellia's website). The total number of patients serviced was reported as 1,716 and the number of discharges was 1,549. Total revenue was reported as \$221,966. (Please refer to Attachment 4.Section B.Project Description.Item ID.Camellia JAR 2013 for Camellia's 2013 Joint Annual Report.)

E. The applicant mentions feedback from physicians and manufacturers. Letters of support from 2 manufacturers is noted, however, the requested letters from physicians have yet to be provided by the applicant. Given the importance of the proposed service as an extension of the physician and the requirement for letters of support from physicians in the project-specific criteria for home health agencies, please explain the difficulty with obtaining physician letters of support for the proposed HHA.

IPM has found a difficulty with obtaining physician letters of support because physicians are reluctant to sign a letter of support for a company that does not have proper licensure in place yet. Once the proper licensure is in place, IPM does not foresee an issue with obtaining letters from support from MDs.

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F. What insight was obtained from the Tennessee Medical Association and Tennessee Hospital Association, if any? Please discuss.

Information cannot be accessed because IPM is not a member of either association. Information is only provided to members.

G. The applicant is proposing a statewide, topographically diverse service area covering all rural and urban Tennessee counties. The discussion of the applicant's plans to cover Tennessee with 1 FTE per 40-50 patients located within a 180 mile radius of the RN's work location is noted. With approximately 120 patients projected for Year at 12 visits each, it appears that the applicant could staff with 3 RNs at most. Please identify the potential locations of the 3 RNs envisioned in the first year of the project that meet the criteria. As a suggestion, it may help to show the RN base locations with 180 mile radius circles on a map of the state.

Locations of RN's within 1st year:

- Henderson, TN (Chester County)
- Woodbury, TN (Cannon County)
- Newport, TN (Cocke County)
- H. The use of a web portal with communication via e-mail or phone is described in the response for Item 5.H. Please address the method for observing confidentiality & compliance with HIPAA.

The MD will have 24/7 access to their patients information via IPM's web portal system. Each ordering MD will be given a personal secure user name and password to access information. The MD will ONLY have access to his/her patient's. HIPAA compliance will also be followed using encrypted emails containing confidential information and without any patient information in the subject of the email. Emails containing patient information will ONLY be sent to MD's secured email address in accordance with HIPAA guidelines. The communication of patient information via phone will only be given to MD office directly.

I. The applicant states that the DON/Administrator has responsibility for the administration and implementation of the 24 hour call center. What is the coverage plan for the center? For example, will it be staffed 24/7 by IPM employees or by contract with a non-related party? What are target response times to notify clinical staff and resolve problems issues that may arise? In your response, please provide examples of IPM protocols or policies & procedures used in other markets to help illustrate the nature & scope of the call center.

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The DON/Administrator will also be responsible for the 24 on call resource. IPM does not foresee the need for a physical "call center." The "call center" is a virtual one in which all calls are directed to the DON/Administrator's cell phone. Since the DON/Administrator will be responsible for the 24/7 on-call service, IPM does not foresee a need at this time to contract with a non-related third party. The DON/Administrator will respond to calls within 20 minutes and work on immediate resolution of the problem/issue.

IPM On-Call Protocol:

- An incoming call is received by IPM after hours and caller is able to leave a message for "an on-call clinician".
- The DON's cell phone rings notifying her that an after-hours message is received.
- The DON then retrieves the on-call message by listening to his/her personal voicemail and returns call to caller within 20 minutes for immediate resolution of the issue.
- The DON will dispatch an RN if immediate implementation is required.
- J. The clinical staff training & experience requirements are noted. Is experience in home health setting mandatory for candidates?

Being that intrathecal infusion therapy nursing will be the only service provided by IPM, only adequate training for intrathecal infusion will be mandatory for RN candidates. Although prior experience in home health care settings is preferred, it will not be required.

6. Section B, Project Description, Item II.A.

The clinical staffing plan description (for RNs) is noted. Taking into account the 120 projected patients in Year 1, it appears that RN staffing might reach 3 RNs if the projected census is reached by the end of the year. This is based on the staffing ratio you identified at 40-50 patients per RN. Please confirm.

Yes, this is correct. There is a potential for the RN staffing to reach 3 RN's by the end of year one.

The applicant also stated that it had physician providers in place. Please describe the nature and scope of the arrangements with physicians. Will some form of contractual agreement between the parties be used to document the responsibilities of the parties? If so, please provide a copy of same. At a minimum, a letter of interest from physician(s) that addresses their interest and ability to participate in the project would be appreciated.

Physicians who manage intrathecal infusion pumps in the state of Tennessee have been identified by IPM. There are no current "arrangements" with physicians at this time due to non-licensure status. Once IPM obtains the proper licensure, we will then notify the physicians of our services. If a physician decides to refer a patient to IPM

Melissa Hess August 14, 2014 Page 8

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services, at this time a Coordination of Care contract will be executed (see Attachment 6.Project Description.Item IIA for a template of this agreement). If a physician decides to refer a patient to IPM for intrathecal home infusion services, then IPM will utilize the physicians signed order as the "contractual document." On every physician order, the physician must include the following statement "IPM RN to maintain intrathecal infusion pump including refills and reprogramming as ordered by MD." At this time, IPM has not found an MD that is willing to sign a letter of support for a company that is not currently licensed by the state.

The applicant states that it intends to use contracted infusion therapy services that include the following: medication compounding, processing of orders, dose titrations and changes and patient medication counseling. Please document the relationship between the parties by providing a copy of a draft working agreement, memorandum of understanding or similar form of documentation. At a minimum, a letter of interest from the compounding pharmacy(s) that addresses its interest and ability to provide the services needed would be appreciated.

IPM will use a designated pharmacy to provide all pharmacy services including: medication compounding; processing of orders; and consultation with the appropriate dispensing physician, patient, and IPM clinical staff. This said pharmacy will independently bill for its services to either the patient or the patient's insurance company.

IPM has drafted a contract template for the aforementioned services (see Attachment 4.Section B.Project Description.Item 1.Pharmacy Contract). We also have one interested party, ICS (see Attachment 4.Section B.Project Description.Item 1.Pharmacy Brochure for facility information), that specializes in intrathecal infusion drug compounding. We have provided evidence that this pharmacy is ready and willing to contract with us for these services at this time (please refer to Attachment 4.Section B.Project Description.Item 1.Pharmacy Letter).

7. Section B, Project Description, Item II.C.

The responses to Items 6.A-6.C are noted. For item B, some idea of metrics pertaining to health care delivery cost savings or benefits would be appreciated. Based on the applicant's experience in other states and pending JCAHO accreditation, please provide examples of metrics for reductions in ER visits, reduction of infections, reduction of hospital stays.

IPM will be unable to provide the requested data for such comparisons until we have serviced a sufficient number of patients from which we can obtain it. In light of this, we have attached appropriate supporting documentation indicating the efficacy of our particular type of service—intrathecal infusion therapy within the home—and, in turn, a need for such services where none is provided.

Please see the attached graph indicating decreased hospital stays while utilizing home infusion therapy for intrathecal pump management (see Attachment 7.Section B.Project Description.Item IIC.Homecare Graph). We have included an article documenting the underutilization of Intrathecal Baclofen therapy as an under-

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recognized treatment modality for multiple sclerosis (Attachment 7.Section B.Project Description.Item IIC.Too Little Too Late). Cost savings attributed to the increased efficacy of intrathecal infusion therapy for children diagnosed with cerebral palsy are cited in two attached articles (see Attachment 7.Section B.Project Description.Item IIC.Medical Expenditures and Attachment 7.Section B.Project Description.Item IIC.Children and Youth).

8. Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services, Items 1 through 4)

The responses to these 4 standards are noted. However, the application cannot be deemed complete unless and until the information being requested for the proposed state-wide service area is provided. Because the scope of the project includes the creation of a home health agency, a basic requirement for all HHA's seeking Certificate of Need approval for new or expanded services is to address the project specific criteria for home health agencies as published in Tennessee's Guidelines for Growth. Discussion about whether or not the applicant's proposed HHA limited to intrathecal pump home infusion management services will be eligible for special consideration will be determined by HSDA Agency Board members when your application is heard. For your convenience, the questions are repeated from the HSDA first supplemental questionnaire sent on 7/22/14. Please see the questions below:

Review of the Tennessee Department of Health "Licensed Facilities" report on the Department's website revealed that there are 157 home health agencies (HHA) presently licensed to serve In Tennessee.

Exhibit 1 below was provided in the attachments to the 7/28/14 supplemental response. However, the exhibit is missing the licensed number of counties served by each active HHA license and the utilization of each HHA as reported to the Tennessee Department in the provider Joint Annual Report for the most recent consecutive 3 year periods (2010-2012). All this information can be obtained on the link to the Department of Health contained in the HSDA website under "Applicant's Toolbox".

For # of counties served, Alecia Craighead, HSDA Statistician III, provided a spreadsheet that was sent with the HSDA 7/21/14 supplemental questionnaire. The spreadsheet identifies all licensed HHAs for each of Tennessee's 95 counties (as of 7/20/14). Please note that the # of HHAs by county is also identified in Exhibit II. Please revise Exhibit 1 with the information requested. If you have any questions about the agency listing, please contact Alecia Craighead, HSDA Statistical Analyst at 615-253-2782 to discuss further.

In Exhibit 1, we have bolded "Camellia Home Health of East Tennessee, LLC" as this is the only Home Health Agency licensed within the state of Tennessee that provides intrathecal home infusion services. You will notice that Camellia's parent office is located in Hattiesburg, MS as its license states on the Tennessee Department of Health website, http://health.state.tn.us, under Facility Listings (see

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Attachment 4.Section B, Project Description, Item ID.Camellia License Info). Please reference the attached Joint Annual Reports for this agency from 2010, 2011, and 2012 from which we derived this information (Attachment 8. Section C.Need.Item 1A.Camellia JARs).

We have chosen to represent Camellia as servicing 28 counties in total in Exhibit 1 as this is the current number stated on the TN Department of Health website, despite their listing of 22 as the total number of counties serviced within their 2013 JAR (see Attachment 4.Section B.Project Description.Item ID.Camellia JAR 2013).

Exhibit 1
Existing Licensed HHAS & Their Utilization serving the 95 County Declared Service Area

Agency Name (license #)*	County of Parent Office	Total Counties authorized in license (# counties in service area) **	2010 JAR Total patients served	2011 JAR Total patients served	2012 JAR Total patients served
Clinch River Home Health #00000001 (01032)	Anderson	7	596	473	468
Professional Case Management of Tennessee #00000620 (01042)	Anderson	8	105	127	182
Heritage Home Health #00000004 (02024)	Bedford	7	286	282	280
Tennessee Quality Homecare - Northwest #00000008 (03025)	Benton	15	1129	1129	1128
Blount Memorial Hospital Home Health Services #00000213 (05012)	Blount	19	1299	1357	1308
Family Home Care, Cleveland #00000013 (06043)	Bradley	5	594	673	1023
Home Health Care of East Tennessee, Inc. #00000014 (06043)	Bradley	17	4976	4764	4755
Sunbelt Homecare #00000016 (07032)	Campbell	10	246	285	260
Baptist Memorial Home Care #00000019 (09065)	Carroll	11	245	235	213
Amedisys Home Health Care #00000023 (10031)	Carter	7	1523	1241	1147
Amedisys Home Health of Tennessee #00000025 (13022)	Claiborne	5	1272	1730	2074
Claiborne Home Health Care	Claiborne	N/A	504	436	unavailable

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(13032)					
Cumberland River Homecare #00000135 (14024)	Clay	10	313	361	236
Smoky Mountain Home Health and Hospice, Inc. #00000027 (15032)	Cocke	12	1699	1622	1535
Doctor's Associates Home Health (16034)	Coffee	N/A	787	unavailable	unavailable
Medical Home Health Care (16024)	Coffee	N/A	1002	726	unavailable
C.M.C. Home C.A.R.E. #00000033 (18054)	Cumberland	Facility Closed	545	536	409
Alere Women's and Children's Health LLC #00000471 (19654)	Davidson	14	349	140	196
Amedisys Home Care #00000038? (19674)	Davidson	22	2881	1538	1598
Amedisys Home Health #00000068? (19024)	Davidson	10	1443	756	388
Amedisys of Nashville East #00000040 (19684)	Davidson	Facility Closed	701	unavailable	unavailable
Continuous Care Services, LLC #00000048 (19664)	Davidson	6	788	905	671
Elk Valley Health Services, Inc. #00000042 (19494)	Davidson	95	547	250	245
Friendship Home Healthcare, Inc. #00000323 (19614) N/A	Davidson	14	769	1040	1093
Friendship Private Duty, Inc. (19714)	Davidson	Facility Closed	9	10	unavailable
Gentiva Health Services #00000049 (19084)	Davidson	12	1345	1239	1239
Home Care Solutions #0000056 (19544)	Davidson	95	2140	unavailable	2080
Home Health Care of Middle Tennessee, LLC #00000046 (19584)	Davidson	14	4017	4246	3914
Intrepid USA Healthcare Services #00000034 (19364)	Davidson	19	386	644	920
Maxim Healthcare Services, Inc. #00000615 (19704)	Davidson	9	154	138	141
Premiere Home Health, Inc. #00000035 (19374)	Davidson	1	113	118	81
SunCrest Home Health #0000070 (19324)	Davidson	12	4728	5428	6710
US Bioservices (19504)	Davidson	N/A	N/A	unavailable	unavailable
Vanderbilt Community and Home Services #00000043 (19394)	Davidson	20	1155	1180	1230
Vanderbilt Home Care Services #00000065 (19314)	Davidson	7	1049	1179	1268
Willowbrook Home Health	Davidson	36	3413	3088	2149

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Care Agency, Inc. #00000259					
(19694)					
Tennessee Quality Homecare – Southwest #00000221 (20045)	Decatur	15	1352	1352	1082
Volunteer Homecare of West Tennessee, Inc. #00000063 (20055)	Decatur	17	1401	1598	1503
SunCrest Home Health #00000060 (21024)	DeKalb	7	1282	1406	1501
Regional HomeCare, Dyersburg #00000077 (23035)	Dyer	6	655	744	814
NHC Homecare #00000291 (24026)	Fayette	8	254	254	217
Where The Heart Is, Inc. #00000612 (24036)	Fayette	3	34	253	284
Quality Home Health #00000287 (25044)	Fentress	16	4059	4540	4012
Quality Private Duty Care #00000080 (25034)	Fentress	5	461	599	703
Amedisys Home Care #00000082 (26054)	Franklin	16	1197	1015	1074
Caresouth HHA Holdings of Winchester, LLC #00000083 (26024)	Franklin	34	1229	1395	1371
NHC Homecare #00000085 (27025)	Gibson	12	546	479	625
Volunteer Home Care, Inc. #00000285 (27085)	Gibson	13	2443	2549	3027
Advanced Home Care, Inc. #00000086 (30021)	Greene	7	323	385	526
Laughlin Home Health Agency #00000088 (30041)	Greene	5	608	553	547
Procare Home Health Services #00000087 (30051)	Greene	6	323	418	384
Amedysis Home Health Care #00000091 (32102)	Hamblen	13	3494	3613	3675
Premier Support Services, Inc. #00000010 (32132)	Hamblen	30	839	972	900
University of TN Medical Center Home Health Services #00000153 (32122)	Hamblen	20	663	unavailable	1244
Alere Women's and Children's Health, LLC #00000457 (33423)	Hamilton	13	6	18	52
Amedysis Home Health #00000113 (33103)	Hamilton	21	2907	3358	3343
Continucare Healthservices, IncI #0000098 (33213)	Hamilton	8	1537	1638	1494
Continucare Healthservices,	Hamilton	11	18	21	17

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			7	T	
IncII #00000108 (33383)					
Gentiva Health Services	Hamilton	12	459	487	268
#00000100 (33093)		-			
Guardian Home Care, LLC	Hamilton	7	2122	2179	2116
#00000115 (33083)		1			
Home Care of Chattanooga	Hamilton	17	223	208	119
#00000014 (33133)		1			
Home Care Solutions	Hamilton	10	401	unavailable	734
#00000338 (33363)		10			
Life Care at Home of		10	770	(1)	000
Tennessee #00000109	Hamilton		772	616	989
(33303)		-			
Maxim Hospital Home	Hamilton	8	106	71	150
Health #00000613 (33433)		-			
Memorial Hospital Home	Hamilton	11	3448	3469	3264
Health #00000103 (33253)					
NHC Homecare #00000111	Hamilton	11	207	199	203
(33033)	114111111111				
Hancock County Home		4			
Health Agency #00000117	Hancock	1	342	299	323
(34011)					
Deaconess Homecare	Hardin	11	1124	1213	1244
#00000290 (36025)	11010111				
HMC Home Health, LLC	Hardin	6	308	252	274
#00000137 (36035)	Turum		1200		
Hometown Home Health		3			
Care, Inc. #00000320	Hawkins		177	173	unavailable
(37021)					
Regional Home Care,		22			
Lexington #00000139	Henderson		683	579	616
(39035)					
Henry County Medical Center		12			
Home Health #00000122	Henry		474	355	399
(40075)					
Hickman Community Home	Hickman	N/A	154	9	134
Care, Inc. (41034)	THORMAN		10.		
Johnson County Home Health	Johnson	2	408	251	396
#00000130 (46031)	Johnson		100	201	
Amedisys Home Health Care	Knox	28	4958	3470	5420
#00000150 (47202)	Kliox		1,500	3170	
CareAll Home Care Services	Knox	6	277	177	278
#00000131 (47232)	KIIOX		217	1	
Covenant Homecare	Knox	17	3940	2254	3946
#00000133 (47402)	THIO!		100.0	ļ	
East Tennessee Children's		16			
Hospital Home Health Care	Knox		1066	319	559
#00000132 (47222)					
Gentiva Health Services	Knox	16	812	636	870
#00000142 (47042)	AMIOA		1012	1000	
Girling Health Care Services	Knox	27	1	0	1
of Knoxville, Inc. #00000149	1240/4		1	L	

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(47372)					
Girling Health Care, Inc. (47182)	Knox	N/A	1130	760	1031
Maxim Healthcare Services, Inc. #00000149 (47182)	Knox	18	210	83	150
NHC Homecare #00000143 (47012)	Knox	15	573	352	567
Priority Healthcare Services of Tennessee, Inc. (47062)	Knox	N/A	1513	unavailable	unavailable
St. Mary's Home Care Services (47092)	Knox	Withdrew Application	4206	unavailable	unavailable
University of TN Medical Center Home Care Services #00000156 (47132)	Knox	16	1877	1492	3264
Deaconess Homecare #00000161 (52024)	Lincoln	25	604	381	704
Hospital Home Health and Hospice (52044)	Lincoln	N/A	259	210	unavailable
NHC Homecare #00000166 (54043)	McMinn	8	234	117	183
Woods Home Health LLC (54083)	McMinn	N/A	N/A	177	unavailable
Amedisys Home Health Care #00000177	Madison	19	2407	1618	2586
Extendicare Home Health of West Tennessee #00000120 (57095)	Madison	21	1015	unavailable	993
Intrepid USA Healthcare Services (57165)	Madison	N/A	210	168	86-1
Medical Center Home Health, LLC 00000174 (57055)	Madison	17	1329	810	1617
Regional Home Care, Jackson #00000178 (57085)	Madison	20	969	755	1061
CareAll Homecare Services #00000194 (60074)	Maury	18	354	285	224
Maury Regional Home Services #00000180 (60044)	Maury	8	1022	1188	1220
NHC Homecare #00000181 (60024)	Maury	21	2150	2212	2134
Quality First Home Care #00000090 (60084)	Maury	5	877	906	855
Intrepid USA Healthcare Services #00000190 (62052)	Monroe	15	240	238	273
Sweetwater Hospital Home Health #00000189 (62062)	Monroe	5	470	462	569
Gateway Home Health, Clarksville #00000186 (63034)	Montgomery	7	873	1050	1067
Extendicare Home Health of Western Tennessee #00000188 (66035)	Obion	5	499	398	347

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Amedisys #00000191	0	11	1255	1325	1277
(67024)	Overton		1355	1323	12//
Highland Rim Home Health Agency #00000197 (71014)	Putnam	14	597	555	495
Intrepid USA Healthcare Services #00000198 (71084)	Putnam	8	275	244	341
Lifeline Home Health Care #00000203 (74064)	Robertson	5	325	289	336
NHC Homecare #00000205 (74054)	Robertson	7	830	869	909
Amedisys #00000207 (75054)	Rutherford	7	613	543	554
Amedisys Home Health Care #00000005 (75064)	Rutherford	19	1315	1476	1431
NHC Homecare #00000208 (75024)	Rutherford	24	2794	3007	3269
Deaconess Homecare #00000211 (76032)	Scott	5	402	406	352
Accredo Health Group, Inc. #00000347 (79456)357	Shelby	6	7	9	14
Alere Wom892en's and Children's Heal2411th LLC #00000459 (79466)576	Shelby	7	4	357	401
Amedisys Home Care #00000239 (79146)	Shelby	3	789	892	938
Amedisys Home Health #00000215 (79386)	Shelby	3	2344	2411	1806
Amedisys Home Health Agency, Inc. #00000238 (79256)	Shelby	4	567	576	683
Baptist Trinity Home Care #00000241 (79276)	Shelby	4	3314	3248	3367
Baptist Trinity Home Care – Private Pay Division #00000242 (79446)	Shelby	5	1	1	1
Best Nurses, Inc. #00000621 (79546)	Shelby	3	41	311	366
Elder Care, Inc. (79136)	Shelby	N/A	421	780	unavailable
Family Home Health Agency #00000229 (79206)	Shelby	2	1070	375	863
Functional Independence Home Care, Inc. #00000610 (79496)	Shelby	3	903	unavailable	804
Home Health Care of West Tennessee, Inc. #00000227 (79486)	Shelby	4	1617	unavailable	1118
Homechoice Health Services #00000240 (79376)	Shelby	6	2963	unavailable	unavailable
Interim Healthcare of Memphis, Inc. #00000228 (79056)	Shelby	3	727	720	889

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Intrepid USA Healthcare	ř –	3			<u> </u>
Services #00000214 (79226)	Shelby]	537	662	615
Maxim Healthcare Services, Inc. #00000618 (79536)	Shelby	6	82	103	197
Methodist Alliance Home Care #00000233 (79316)	Shelby	7	3352	3226	3180
No Place Like Home, Inc. #00000611 (79506)	Shelby	3	48	38	55
Senior Services Home Health (79106)	Shelby	N/A	670	642	127
Still Waters Home Health Agency, LLC #00000616 (79526)	Shelby	1	83	105	unavailable
Willowbrook Visiting Nurse Association, Inc. #00000244 (79236)	Shelby	6	451	479	533
Sumner Homecare and Hospice, LLC (Highpoint Homecare) #00000245 (80064)	Smith	8	316	212	unavailable
Advanced Home Care, Inc. #00000249 (82051)	Sullivan	5	2665	2825	2583
Gentiva Health Services #00000251 (82061)	Sullivan	9	1244	1286	979
Sumner Homecare and Hospice, LLC #00000258 (83114)	Sumner	7	1102	978	unavailable
Baptist Home Care and Hospice – Covington #00000260 (84046)	Tipton	8	330	326	361
CareAll Homecare Services #00000288 (84076)	Tipton	19	1424	1491	unavailable
Unicoi County Home Health #00000355 (86051)	Unicoi	1	205	246	209
CareAll Home Care Services #00000265 (89074)	Warren	10	515	520	337
Friendship Home Health, Inc. #00000619 (89084)	Warren	10	1083	1025	1345
Intrepid USA Healthcare Services #00000263 (89064)	Warren	16	506	650	159
Amedisys Home Health #00000273 (90121)	Washington	7	2905	2496	2384
Medical Center Homecare Services #00000271 (90091)	Washington	6	2667	2801	3118
Medical Center Homecare, Kingsport #00000269 (90081)	Washington	7	1298	1126	1628
NHC Homecare #00000267 (90131)	Washington	7	279	241	264
CareAll Homecare Services #00000276 (92025)	Weakley	13	1902	1903	unavailable

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Guardian Home Care of Nashville, LLC #00000607 (94074)	Williamson	14	1982	1265	1365
Home Health Care Services, LLC (Health at Home) #00000617 (94094)	Williamson	1 ::	62	63	unavailable
CareAll (95064)	Wilson	N/A	1680	1473	unavailable
Deaconess Homecare #00000282 (95034)	Wilson	21	1076	1237	1210
Donelson Home Health (95074)	Wilson	N/A	1931	1705	unavailable
Quality Care Home Health Agency (95084)	Wilson	N/A	128	217	unavailable
Camellia Home Health of East Tennessee, LLC #00000144 (47062)	Out-of- State (MS)	28	1513	1448	1556
Magnolia Regional Health Center Home Health #00000296 (96010)	Out-of-State	2	1009	1000	915
Professional Home Health Care Agency, Inc. #00000298 (96030)	Out-of-State	7	2920	3021	2985
Regional Home Care Parkway #00000297 (96020)	Out-of-State	2	23	31	14

^{*} Please highlight any HHA in bold font that offers intrathecal home infusion services, even if on a limited basis.

** Please show the # of all counties for each HHA. The # of counties in the applicant's service area should be shown separately in the bracket.

The applicant must also complete Exhibit II to address the need standard in the project specific criteria for Home Health Agency services. This Exhibit is provided to help the applicant identify all existing licensed HHAs authorized to serve the statewide service area in, to apply the need formula correctly and to identify the net need (surplus or shortage) for any additional agencies at this time and four years in the future (CY2018). Please complete the table as requested.

IPM utilized population demographics information from the US Census Bureau as well as from the Applicant Toolbox on the HSDA website (please see Attachment 8. Section C.Need.Item 1A.US Census Quickfacts).

In comparison with the Tennessee Department of Health's 2013 Final Joint Annual Report (JAR) population projections per county (see Attachment 8. Section C.Need.Item 1A.2013 Final JAR), reflects an overall similarity in IPM's population projections for all counties. You will notice, however, that the data we collected from the prior published JAR has three discrepant pieces of data as reported in Clay, Franklin and Greene Counties. The estimated population seems to be very similar but the total patients served in those counties are much higher

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than the estimated population (ex. Clay has an estimated population of 7,673 with 103,667 total patients served). We do not believe this will affect Tennessee cumulatively if the data is correct but simply hasn't been divided into counties in exact proportions.

			V	hibit 2				
County (A)	# Authorized Agencies*	2014 Pop*	Patients served -2013 (D)	Use Rate (Patient /1000 pop.) (E)	(F)	Projected Capacity (G)	Projected Need (H)	Additional Need (Surplus) fo 2018 (G-H)
Please list all 95 counties Examples are provided for the eastern division of TN below				(Column D Divided by Column C)		Column E Times Column F	Column F Times 0.015	Column G Minus Column H
114 Delow	aring provide a	100	in Day	A Property of	//	100/1		2.
ra anno				o wa fa -				
Anderson	24	76,579	582	0.0075999	77,851	591.66719	1167.765	-576.097807
Bedford	25	47,368	241	0.0050878	50,566	257.27085 8	758.49	-501.219142
Benton	16	16,257	1164	0.0715999	16,104	1153.0452 1	241.56	911.485211
Blount'	19	128,368	1224	0.0095350	135,171	1288.8671	2027.565	-738.697806
Bradley	20	103,308	4593	0.0444592	107,481	4778.5286	1612.215	3166.31360 4
Campbell	24	41,474	341	0.0082220	42,566	349.97844 4	638.49	-288.511556
Cannon	25	14,125	0	0	14,540	0	218.1	-218.1
Carroll	16	28,119	262	0.0093175 4	27,831	259.31654 8	417.465	-158.148452
Carter	12	57,284	1171	0.0204420	57680	1179.0950 4	865.2	313.895035 3
Cheatham	31	39,853	0	0	40765	0	611.475	-611.475
Chester	15	17,472	0	0	17999	0	269.985	-269.985

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Claiborne	23	32,604	2682	0.0822598	33280	2737.6076	499.2	2238.40765
Clay	11	7,702	103667	13.459750 7	7673	103276.66 7	115.095	103161.572
Cocke	19	36,762	1296	0.0352537 9	38615	1361.3252 8	579.225	782.100281 5
Coffee	23	54,273	3865	0.0712140 5	56841	4047.8776 7	852.615	3195.26267 4
Crockett	15	14,596	0	0	14683	0	220.245	-220.245
Cumberland	20	57,815	407	0.0070397	60292	424.43732 6	904.38	-479.942674
Davidson	37	656,385	25202	0.0383951 5	682330	26198.162 1	10234.95	15963.2121 5
Decatur	17	11,822	2614	0.2211131 8	12080	2671.0472	181.2	2489.8472
DeKalb	29	18,952	3537	0.1866293 8	19125	3569.2868 8	286.875	3282.41188 3
Dickson	29	50,860	0	0	51964	0	779.46	-779.46
Dyer	14	38,218	702	0.0183683 1	38427	705.83897 6	576.405	129.433976 4
Fayette	30	40,930	499	0.0121915 5	44888	547.25414 1	673.32	-126.065859
Fentress	15	18,404	3404	0.1849597 9	18987	3511.8315 6	284.805	3227.02655 8
Franklin	19	41,230	50467	1.2240359	42122	51558.84	631.83	50927.0100 2
Gibson	17	51,102	3616	0.0707604 4	52163	3691.0768 3	782.445	2908.63182 7
Giles	14	29,315	0	0	29285	0	439.275	-439.275
Grainger	22	23,111	0 '	0	23675	0	355.125	-355.125
Greene	21	70,187	177437	2.5280607 5	71594	180993.98 1	1073.91	179920.071 5
Grundy	26	13,355	0	0	13293	0	199.395	-199.395
Hamblen	21	64,108	6392	0.0997067 4	65570	6537.7712 6	983.55	5554.22126 1
Hamilton	21	347,451	12394	0.0356712	353577	12612.521 9	5303.655	7308.86687 5
Hancock	20	6,652	537	0.0807276	6640	536.03126 9	99.6	436.431268 8
Hawkins	22	57,509	96	0.0016693	58164	97.093394 1	872.46	-775.366606
Haywood	20	18,117	0	0	18009	0	270.135	-270.135
Henderson	13	28,186	0	0	28631	0	429.465	-429.465
Henry	15	32,697	374	0.0114383 6	32956	376.96253 5	494.34	-117.377465
Hickman	25	24,422	214	0.0087625	24698	216.41847	370.47	-154.051525

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			1	9	Î	5	1	1
Houston	16	8,388	0	0	8447	0	126.705	-126.705
Humphreys	20	18,498	0	0	18561	0	278.415	-278.415
Jackson	15	11,368	0	0 -	11495	0	172.425	-172.425
Jefferson	19	53,729	0	0	56872	0	853.08	-853.08
Johnson	11	18,094	12247	0.6768542	18127	12269.336	271.905	11997.4311
Knox	25	453,629	18026	0.0397373	475569	18897.836 8	7133.535	11764.3017
Lake	8	9,732	0	0	9468	0	142.02	-142.02
Lauderdale	19	27,341	0	0	27125	0	406.875	-406.875
Lawrence	16	42,329	0	0	42387	0	635.805	-635.805
Lewis	16	12,112	0	0	12224	0	183.36	-183.36
Lincoln	16	34,281	1189	0.0346839	35697	1238.1124	535.455	702.657453
Loudon	25	50,926	0	0	53192	0	797.88	-797.88
McMinn	24	53,233	529	0.0099374	54203	538.63932	813.045	-274.405679
McNairy	17	26,582	0	0	27299	0	409.485	-409.485
Macon	23	23,188	0	0	24121	0	361.815	-361.815
Madison	20	99,555	7118	0.0714981	101001	7221.3863 5	1515.015	5706.37134
Marion	19	28,556	0	0	28992	0	434.88	- 434.88
Marshall	24	31,286	0	0	321015	0	4815.225	-4815.225
Maury	26	82,280	5158	0.0626883	83256	5219.1838 6	1248.84	3970.34386
Meigs	23	12,205	0	0	12643	0	189.645	-189.645
Monroe	21	46,092	971	0.0210665 6	48088	1013.0488 6	721.32	291.728858 8
Montgomery	25	187,649	17349	0.0924545	200566	18543.235 2	3008.49	15534.7451 6
Moore	14	6,350	0	0	6401	0	96.015	-96.015
Morgan	25	21,848	0	0	22004	0	330.06	-330.06
Obion	14	31,453	302	0.0096016	31222	299.78202 4	468.33	-168.547976
Overton	14	22,489	1453	0.0646093	22967	1483.8832	344.505	1139.37827 6
Регту	14	8,014	0 ,	0	8096	0	121.44	-121.44
Pickett	13	5,019	0	0	4943	0	74.145	-74.145
Polk	17	16,604	0	0	16588	0	248.82	-248.82

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Putnam	20	77,024	356	0.0046219	82623	381.87822	1239.345	-857.46678
Rhea	22	33,392	0	0	34790	0	521.85	-521.85
Roane	26	54,006	0	0	54457	0	816.855	-816.855
Robertson	31	70,391	1803	0.0256140 7	74371	1904.944	1115.565	789.378998 5
Rutherford	38	293,582	6098	0.0207710 3	329446	6842.9321 6	4941.69	1901.24215 5
Scott	21	21,944	394	0.0179547 9	21969	394.44887	329.535	64.9138698 5
Sequatchie	20	15,019	0	0	16004	0	240.06	-240.06
Sevier	18	94,833	0	0	100362	0	1505.43	-1505.43
Shelby	28	943,812	20342	0.0215530 2	954012	20561.840 8	14310.18	6251.66081 6
Smith	25	19,618	377	0.0192170 5	20281	389.74090 1	304.215	85.5259012 1
Stewart	12	13,549	0	0	13941	0	209.115	-209.115
Sullivan	15	158,975	5123	0.0322251 9	161136	5192.6386 4	2417.04	2775.59864 1
Sumner	32	172,262	855	0.0049633 7	183406	910.31179 3	2751.09	-1840.77821
Tipton	29	63,865	1915	0.0299851	67545	2025.3452 6	1013.175	1012.17026
Trousdale	24	8,167	0	0	8582	0	128.73	-128.73
Unicoi	14	18,376	351	0.019101	18511	353.57863 5	277.665	75.9136351 8
Union	24	19,301	0	0	19605	0	294.075	-294.075
Van Buren	18	5,450	0	0	5474	0	82.11	-82.11
Warren	27	40,489	1307	0.0322803 7	41155	1328.4987 3	617.325	711.173728
Washington	16	130,586	2085	0.0159664 9	138370	2209.2831 5	2075.55	133.733154 4
Wayne	12	16,854	0	0	16724	0	250.86	-250.86
Weakley	18	38,522	2036	0.0528529	39491	2087.2144 7	592.365	1494.84947 5
White	21	26,871	0	0	27974	0	419.61	-419.61
Williamson	36	202,923	1541	0.0075940 1	223333	1695.9938 2	3349.995	-1654.00118
Wilson	36	124,073	7014	0.0565312	133357	7538.8359 9	2000.355	5538.48099 2
Total	1907	6,523,68 6	524919	0.0804635 6	7,057,60 4	567879.94 3	105864.1	462015.883

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Attachment C.Need-Item 1.c.

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9. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

The clarifying information with letters of support from the 2 pump manufacturers and two patients is noted.

Letters from physicians and other referral sources such as HHAs should also be provided as requested in the following standards. Please note the following:

A. The applicant <u>shall</u> provide letters of intent from physicians and other referral sources pertaining to patient referral.

Our initial referrals will come directly from the pump manufacturer representatives, in which you have noted to have received their letters of support. You have also noted to have received letters of support from patients (see Attachment 9.Section C.Need.Item 1A). IPM has found that at this time, physicians are not comfortable recommending a company that does not have the proper licensure in place in the state. Therefore, letters of support from physicians will not be available until licensure is obtained.

B. The applicant <u>shall</u> provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The pump manufacturer representatives will be providing IPM with the initial referrals from surgeons implanting new pumps. The implanting surgeon will continue to manage these individuals in conjunction with IPM's proposed services for intrathecal homecare management. The projected number of cases in the initial year of operation referred by implanting surgeons is projected at 60 cases.

Once IPM obtains state licensure, we can anticipate additional referrals to come directly from the MD. Patients in need of an intrathecal pump commonly have a physically disabling condition, and would greatly benefit from home infusion services in which care is delivered to their doorstep, eliminating the need for travel. The projected number of cases by managing physicians in the initial year of operation is approximately 60 cases.

The total number of cases by service category in the initial year of operation is projected to be 120.

C. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

In your response, please be sure that the letters help quantify the "projected number of cases by service category." Please provide the projected number of referrals from these sources.

^{*} The official population source used by HSDA is the TN Dept. of Health, Division of Health Statistics' Population Projections, 2010-2020. This data is available through the applicant's toolbox on the HSDA website.

IPM has obtained a letter from a Medtronic representative evidencing the great difficulty experienced by Tennessee intrathecal pump patients in obtaining IPM's proposed services, specifically due to the specialization of these services (see Attachment 9.Section C.Need.Item 1C). Please note that this representative cites that such patients often require emergency medical care due to the inability to obtain intrathecal services within the home, thus producing poorer patient outcomes.

Please refer also to the previously submitted letters from potential patients indicating a need for our services (see Attachment 9.Section C.Need.Item 1A).

10. Section C. Need, Item 1 (Specific Criteria: Home Health Services- Items 6a and 6b)

Your response shows an average cost of \$100 per visit and an average cost of \$200 per patient. The response also indicates that the range of charges for this type of proposed service is \$150 - \$200. Is the average charge on a per visit or per patient basis? Please clarify. Note: the reply should take into account that the range of charges covers the average cost per visit. It falls below the estimated average cost per patient.

All amounts pertaining to costs and charges are based on the average cost and reimbursement rates for one RN Home Infusion Visit for one patient.

The question asked about a comparison to the prevailing charge for this type of service by providers in Tennessee. Absent any providers in Tennessee (except 1) to compare to, it would be helpful to identify a range of charges for similar services in other states that the applicant is active in.

In any state, the cost for an IPM RN to provide one patient a visit would be approximately \$100.

The current reimbursement in alternate states ranges between \$150-\$200 per single patient visit.

11. Section C, Need, Item 3

The question asked the applicant to identify and justify the reasonableness of the proposed statewide service area using estimates of potential caseloads. While it is understood that confidential information of the pump vendor (Medtronics) cannot be provided, please understand that the applicant should attempt to illustrate the nature and scope of its projected patient caseload as it pertains to the proposed statewide service area. Using the applicant's estimate of 120 patients (1,440 visits) in Year 1 with primary diagnoses relative to pain or intractable spasticity, please justify the service area by providing a breakout of patients by patient county in the proposed 95 county service area of residence for the first year of the project.

County	No. of patients being served by home health agencies in county	% of total patients
Anderson	2893	1.67
Bedford	1120	0.65

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Benton	667	0.39
Blount'	462	1.45
Bradley	2,021	1.17
Campbell	1,715	0.99
Cannon	423	0.24
Carroll	1,246	0.72
Carter	2,072	1.2
Cheatham	772	0.45
Chester	563	0.33
Claiborne	2,002	1.16
Clay	250	0.14
Cocke	1,467	0.85
Coffee	1,874	1.08
Crockett	537	0.31
Cumberland	1,601	0.92
Davidson	14,910	8.61
Decatur	638	0.37
DeKalb	469	0.27
Dickson	1,616	0.93
Dyer	1,671	0.97
Fayette	713	0.41
Fentress	1,015	0.59
Franklin	1,423	0.82
Gibson	1,924	1.11
Giles	1,001	0.58
Grainger	886	0.51
Greene	2,454	1.42
Grundy	529	0.31
Hamblen	2,835	1.64
Hamilton	7,778	4.49
Hancock	682	0.39
Hawkins	2,148	1.24
Haywood	612	0.35
Henderson	1,015	0.59
Henry	1,283	0.74
Hickman	725	0.42
Houston	281	0.16
Humphreys	803	0.46
Jackson	402	0.23
Jefferson	1,749	1.01
Johnson	907	0.52
Knox	9,976	5.76
Lake	325	0.19
Lauderdale	857	0.5
Lawrence	1,667	0.96
Lewis	402	0.23
Lincoln	1,062	0.61
Loudon	1,572	0.91
McMinn	1,807	1.04
McNairy	1,089	0.63

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Macon	849	0.49
Madison	3,121	1.8
Marion	725	0.42
Marshall	816	0.47
Maury	2,410	1.39
Meigs	346	0.2
Monroe	1,517	0.88
Montgomery	2,903	1.68
Moore	97	0.06
Morgan	472	0.27
Obion	1,280	0.74
Overton	741	0.43
Perry	258	0.15
Pickett	271	0.16
Polk	427	0.25
Putnam	2,405	1.39
Rhea	922	0.53
Roane	2,354	1.36
Robertson	1,738	1.00
Rutherford	5,503	3.18
Scott	835	0.48
Sequatchie	413	0.24
Sevier	2,452	1.42
Shelby	18,064	10.44
Smith	708	0.41
Stewart	339	0.2
Sullivan	5,259	3.04
Sumner	4,159	2.40
Tipton	1,298	0.75
Trousdale	431	0.25
Unicoi	659	0.38
Union	371	0.21
Van Buren	240	0.14
Warren	2,266	1.31
Washington	4,181	2.42
Wayne	640	0.37
Weakley	1,180	0.68
White	962	0.56
Williamson	2,813	1.62
Wilson	3,727	2.15
Total	173,108	100%

12. Section C, Need, Item 4.a. and Item 4.b

Item 4.a.: as is the case with the project specific criteria, the applicant must identify the demographics of the proposed statewide service area. As such, please complete the table below that was requested in the 7/21/14 HSDA supplemental questionnaire.

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Medtronic has assured IPM that there are inthrathecal pump patients in almost every county of the state of TN. Medtronic has also assured IPM that currently there are approximately 300 intrathecal pump patients in the state of TN. IPM is unable to obtain per county information based on pump manufacturer's privacy practices. This information can only be obtained from pump manufacturers and unfortunately they are not privileged to release this amount of detailed patient information. manufacturers have only provided us with information based on the overall state of TN, which is what IPM's projected numbers are based off of. We therefore extrapolated the data provided in the below table from population statistics from the HSDA Applicant Toolbox as well as TennCare enrollment data per TN county (see Attachment 12. Section C. Need. Item 4A. TennCare Data).

Demographic Variable/ Geographic Area	Total Population-Current Year	Total Population-Projected Year	Total Population-% change	*Target Population-Current Year	*Target Population- Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income \$	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level %	Persons Below Poverty Level as % of Total
Anderson	76,579	77,851	1.66	582	1167	100%	1.5%	45	44154	14173	1.2	16.7	6
Bedford	47,368	50,566	6.75	241	758	215%	1.5%	40	39635	10562	0.9	18.9	1.6
Benton	16,257	16,104	94	1164	241	-79%	1.5%	45	33663	3408	0.3	20.4	3.1
Blount'	128,368	135,171	5.3	1224	2027	66%	1.5%	45	46347	18622	1.5	12.7	-4.6
Bradley	103,308	107,481	4.04	4593	1612	-65%	1.5%	40	40614	18565	1.5	17.8	.5
Campbell	41,474	42,566	2.63	341	638	87%	1.5%	35	31312	11966	1.0	23.7	6.4
Cannon	14,125	14,540	2.94	0	218	218%	1.5%	45	40998	2791	0.2	16.4	9
Carroll	28,119	27,831	-1.02	262	417	59%	1.5%	45	35595	6648	0.6	19.2	1.9
Carter	57,284	57680	0.69	1171	865	-26%	1.5%	40	32908	11359	0.9	22.8	5.5
Cheatham	39,853	40765	2.29	0	611	611%	1.5%	40	53363	6083	0.5	11.7	-5.6
Chester	17,472	17999	3.02	0	269	270%	1.5%	40	42097	3397	0.3	16.9	4
Claiborne	32,604	33280	2.07	2682	499	-81%	1.5%	40	33563	7948	0.7	23	5.7
Clay	7,702	7673	38	103667	115	-100%	1.5%	40	30184	1992	0.2	19.7	2.4
Cocke	36,762	38615	5.04	1296	579	-55%	1.5%	40	29764	9911	0.8	26	8.7
Coffee	54,273	56841	4.75	3865	852	-78%	1.5%	40	38151	11065	0.9	20.6	3.3
Crockett	14,596	14683	0.60	0	220	220%	1.5%	40	37601	3431	0.3	19.2	1.9
Cumberland	57,815	60292	4.28	407	904	122%	1.5%	40	37963	10327	0.9	16.4	-0.9
Davidson	656,385	682330	3.95	25202	10234	-59%	1.5%	34	46,676	119510	9.9	18.5	1.2
Decatur	11,822	12080	2.18	2614	181	-93%	1.5%	45	34146	2475	0.2	20.9	3.6
DeKalb	18,952	19125	0.91	3537	286	-92%	1.5%	45	36713	4354	0.4	19	1.7
Dickson	50,860	51964	2.17	0	779	779%	1.5%	40	45109	8891	0.7	16	-1.3
Dyer	38,218	38427	.55	702	576	-17%	1.5%	40	38167	9436	0.8	19.2	1.9
Fayette	40,930	44888	9.67	499	673	35%	1.5%	40	56297	5646	0.5	13.2	-4.1
Fentress	18,404	18987	3.17	3404	284	-92%	1.5%	40	27773	5527	0.5	25.4	8.1
Franklin	41,230	42122	2.16	50467	631	-99%	1.5%	40	41625	6418	0.5	15.9	-1.4
Gibson	51,102	52163	2.08	3616	782	-78%	1.5%	40	36981	11115	0.9	18.6	1.3
Giles	29,315	29285	-0.1	0	439	439%	1.5%	40	38014	5422	0.5	18.6	1.3
Grainger	23,111	23675	2.44	0	355	355%	1.5%	35	33185	4923	0.4	20.2	2.9
Greene	70,187	71594	2	177437	1073	-99%	1.5%	45	35613	12977	1.1	22.5	5.2

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Grundy	13,355	13293	-0.46	0	199	199%	1.5%	40	26644	4593	0.4	29	11.7
Hamblen	64,108	65570	2.28	6392	983	-85%	1.5%	35	39316	13027	1.1	18.6	1.3
Hamilton	347,451	353577	1.76	12394	5303	-57%	1.5%	40	46544	55258	4.6	16.2	-1.1
Hancock	6,652	6640	-0.18	537	99	-81%	1.5%	40	22205	2163	0.2	32.7	15.4
Hawkins	57,509	58164	1.14	96	872	808%	1.5%	45	36419	11852	1.0	16.4	-0.9
Haywood	18,117	18009	-0.6	0	270	270%	1.5%	35	32827	5287	0.4	21.2	3.9
Henderson	28,186	28631	1.58	0	429	429%	1.5%	40	37784	6005	0.5	17.5	0.2
Henry	32,697	32956	0.79	374	494	32%	1.5%	40	36593	6910	0.6	17.4	0.1
Hickman	24,422	24698	1.13	214	370	73%	1.5%	40	42330	5376	0.4	16.3	-1
Houston	8,388	8447	0.7	0	126	126%	1.5%	40	34595	1745	0.1	21.7	4.4
Humphreys	18,498	18561	.34	0	278	278%	1.5%	40	41943	3514	0.3	14	-3.3
Jackson	11,368	11495	1.12	0	172	172%	1.5%	45	33363	2592	0.2	24.1	6.8
Jefferson	53,729	56872	5.85	0	853	853%	1.5%	40	38800	10271	0.9	19.2	1.9
Johnson	18,094	18127	.18	12247	271	-98%	1.5%	45	30063	3880	0.3	25.4	8.1
Knox	453,629	475569	4.84	18026	7133	-60%	1.5%	35	47270	62766	5.2	14.2	-3.1
Lake	9,732	9468	-2.71	0	142	142%	1.5%	40	26212	1940	0.2	30.3	13
Lauderdale	27,341	27125	79	0	406	407%	1.5%	40	32987	7212	0.6	26.1	8.8
Lawrence	42,329	42387	.14	0	635	635%	1.5%	35	36663	8658	0.7	18	0.7
Lewis	12,112	12224	.92	0	183	183%	1.5%	40	33956	2636	0.2	19.4	2.1
Lincoln	34,281	35697	4.13	1189	535	-55%	1.5%	40	40904	6607	0.5	16.4	-0.9
Loudon	50,926	53192	4.45	0	797	797%	1.5%	45	49602	7021	0.6	14.6	-2.7
McMinn	53,233	54203	1.82	529	813	53%	1.5%	40	38944	10462	0.9	18.5	1.2
McNairy	26,582	27299	2.70	0	409	409%	1.5%	40	33066	6970	0.6	23.5	6.2
Macon	23,188	24121	4.02	0	361	362%	1.5%	40	35452	5796	0.5	23.5	6.2
Madison	99,555	101001	1.45	7118	1515	-78%	1.5%	35	42348	20997	1.7	18.3	1
Marion	28,556	28992	1.53	0	434	434%	1.5%	40	39817	6300	0.5	19.2	1,9
Marshall	31,286	321015	2.33	0	480	480%	1.5%	40	40687	5629	0.5	17.9	0.6
Maury	82,280	83256	1.19	5158	1248	-75%	1.5%	35	45603	15047	1.2	15.8	-1.5
Meigs	12,205	12643	3.59	0	189	189%	1.5%	45	33492	2703	0.2	23.3	6
Monroe	46,092	48088	4.33	971	721	-25%	1.5%	40	36430	9673	0.8	19.3	2
Montgomery	187,649	200566	6.88	17349	3008	-82%	1.5%	30	49459	23776	2.0	16.2	-1.1
Moore	6,350	6401	.8	0	96	96%	1.5%	35	44977	885	0.1	14.7	-2.6
Morgan	21,848	22004	.71	0	330	330%	1.5%	40	37522	4250	0.4	19.1	1.8
Obion	31,453	31222	73	302	468	55%	1.5%	40	40516	6381	0.5	17.1	-0.2
Overton	22,489	22967	2.13	1453	344	-76%	1.5%	40	34119	4427	0.4	22.1	4.8
Perry	8,014	8096	1.02	0	121	121%	1.5%	45	32101	1796	0.1	24.2	6.9
Pickett	5,019	4943	-1.51	0	74	74%	1.5%	45	34255	990	0.1	21	3.7
Polk	16,604	16588	1	0	248	248%	1.5%	40	37235	3609	0.3	17.8	0.5
Putnam	77,024	82623	7.27	356	1239	248%	1.5%	40	34107	14258	1.2	24.1	6.8
Rhea	33,392	34790	4.19	0	521	521%	1.5%	40	36470	7841	0.7	22.4	5.1
Roane	54,006	54457	.84	0	816	816%	1.5%	40	43017	9790	0.8	14.4	-2.9
Robertson	70,391	74371	5.65	1803	1115	-38%	1.5%	35	52588	11452	1.0	13	-4.3
Rutherford	293,582	329446	12.22	6098	4941	-18%	1.5%	30	55105	36715	3.0	13	-4.3
Scott	21,944	21969	.11	394	329	-16%	1.5%	35	29161	7272	0.6	25.8	8.5
Sequatchie	15,019	16004	6.56	0	240	240%	1.5%	40	33181	3508	0.3	19.3	2
Sevier	94,833	100362	5.83	0	1505	1505%	1.5%	40	43300	15430	1.3	13.4	-3.9
Shelby	943,812	954012	1.08	20342	14310	-29%	1.5%	35	46251	229641	19.1	20.2	2.9
Smith	19,618	20281	3.38	377	304	-19%	1.5%	35	44116	3813	0.3	17.7	0.4
Stewart	13,549	13941	2.89	0	209	209%	1.5%	40	40200	2564	0.2	20	2.7

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Sumner	172,262	183406	6.47	855	2751	221%	1.5%	40	55560	22900	1.9	9.8	-7.5
Tipton	63,865	67545	5.76	1915	1013	-47%	1.5%	40	51847	11468	1.0	14	-3.3
Trousdale	8,167	8582	5.08	0	128	128%	1.5%	35	43613	1637	0.1	13.2	-4.1
Unicoi	18,376	18511	.73	351	277	-20%	1.5%	40	35415	3666	0.3	22.1	4.8
Union	19,301	19605	1.58	0	294	294%	1.5%	35	33456	4382	0.4	22.6	5.3
Van Buren	5,450	5474	.44	0	82	82%	1.5%	40	31940	1203	0.1	22.4	5.1
Warren	40,489	41155	1.64	1307	617	-52%	1.5%	35	34008	9230	0.8	22.9	5.6
Washington	130,586	138370	5.96	2085	2075	-1%	1.5%	35	42995	18964	1.6	17.3	0
Wayne	16,854	16724	77	0	250	250%	1.5%	40	35377	2871	0.2	20.7	3.4
Weakley	38,522	39491	2.52	2036	592	-70%	1.5%	40	35509	6384	0.5	20.5	3.2
White	26,871	27974	4.10	0	419	419%	1.5%	40	34717	5796	0.5	20.1	2.8
Williamson	202,923	223333	10.06	1541	3349	117%	1.5%	40	91146	8690	0.7	5.8	-11.5
Wilson	124,073	133357	7.48	7014	2000	-71%	1.5%	40	61353	14092	1.2	9.3	-8
Service-Area	6,523,686	7,057,604	8.18	524,919	105,864	14552%	1.5%	40	44,140	1,204,364	100	17.3	3#3
Total													
State of TN	6,523,686	7,057,604	8.18	524,919	105,864	14552%	1.5%	40	44,140	1,204,364	100	17.3	
Total													

*Target Population is population that project will primarily serve. For example, nursing home, home health agency, hospice agency projects typically primarily serve the Age 65+ population; projects for the discontinuance of OB services would mainly affect Females Age 15-44; projects for child and adolescent psychiatric services will serve the Population Ages 0-19. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from current year, e.g., if Current Year is 2014, then default Projected Year is 2018

The table below shows an estimated total number of sufferers that Basic Home Infusion can target in each county in Tennessee. A rate of each of the three diseases was calculated using statistics from findings, then calculated to find an estimated number of sufferers in each of the counties in Tennessee. A final total target market is then calculated from the individual diseases in the whole of Tennessee.

Data were obtained utilizing statistics listed on the following websites: www.msnews.org/ms-statistics/ (see Attachment 12.Section C.Need.Item 4B.Multiple Sclerosis), www.cdc.gov/features/dsCerebralPalsy/ (see Attachment 12.Section C.Need.Item 4B.Cerebral Palsy), www.painmed.org/PatientCenter/Facts_on_Pain.aspx (see Attachment 12.Section C.Need.Item 4B.Chronic Pain), and http://www.census.gov/popclock/ (see Attachment 12.Section C.Need.Item 4B.Population Clock). Please note that all data was calculated utilizing a US population total of 318,606,523 as stated on the US Census Bureau Population Clock at the time of analysis.

Multiple Sclerosis, Cerebral Palsy, Chronic Pain Diseases Within the TN: Who We Target									
Tennessee County	Population 2014	Sufferers of MS	Sufferers of CP (Age 5-17)	Sufferers of Chronic Pain					
Anderson	76,579	84	253	25526					
Bedford	47,368	52	156	15789					
Benton	16,257	18	54	5419					
Blount	128,368	141	424	42789					

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Bradley	103,308	114	341	34436
Campbell	41,474	46	137	13825
Cannon	14,125	16	47	4708
Carroll	28,119	31	93	9373
Carter	57,284	63	189	19095
Cheatham	39,853	44	132	13284
Chester	17,472	19	58	5824
Claiborne	32,604	36	108	10868
Clay	7,702	8	25	2567
Cocke	36,762	40	121	12254
Coffee	54,273	60	179	18091
Crockett	14,596	16	48	4865
Cumberland	57,815	64	191	19272
Davidson	656,385	721	2,166	218795
Decatur	11,822	13	39	3941
DeKalb	18,952	21	63	6317
Dickson	50,860	56	168	16953
Dyer	38,218	42	126	12739
Fayette	40,930	45	135	13643
Fentress	18,404	20	61	6135
Franklin	41,230	45	136	13743
Gibson	51,102	56	169	17034
Giles	29,315	32	97	9772
Grainger	23,111	25	76	7704
Greene	70,187	77	232	23396
Grundy	13,355	15	44	4452
Hamblen	64,108	70	212	21369
Hamilton	347,451	382	1,147	115817
Hancock	6,652	7	22	2217
Hawkins	57,509	63	190	19170
laywood	18,117	20	60	6039
Henderson	28,186	31	93	9395
Henry	32,697	36	108	10899
Iickman	24,422	27	81	8141
Houston	8,388	9	28	2796
Iumphreys	18,498	20	61	6166
ackson	11,368	12	38	3789
efferson	53,729	59	177	17910
ohnson	18,094	20	60	6031
Knox	453,629	498	1,497	151210

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Lake	9,732	11	32	3244
Lauderdale	27,341	30	90	9114
Lawrence	42,329	47	140	14110
Lewis	12,112	13	40	4037
Lincoln	34,281	38	113	11427
Loudon	50,926	56	168	16975
McMinn	53,233	58	176	17744
McNairy	26,582	29	88	8861
Macon	23,188	25	77	7729
Madison	99,555	109	329	33185
Marion	28,556	31	94	9519
Marshall	31,286	34	103	10429
Maury	82,280	90	272	27427
Meigs	12,205	13	40	4068
Monroe	46,092	51	152	15364
Montgomery	187,649	206	619	62550
Moore	6,350	7	21	2117
Morgan	21,848	24	72	7283
Obion	31,453	35	104	10484
Overton	22,489	25	74	7496
Perry	8,014	9	26	2671
Pickett	5,019	6	17	1673
Polk	16,604	18	55	5535
Putnam	77,024	85	254	25675
Rhea	33,392	37	110	11131
Roane	54,006	59	178	18002
Robertson	70,391	77	232	23464
Rutherford	293,582	323	969	97861
Scott	21,944	24	72	7315
Sequatchie Sequateria	15,019	17	50	5006
Sevier	94,833	104	313	31611
Shelby	943,812	1037	3,115	314604
Smith	19,618	22	65	6539
Stewart	13,549	15	45	4516
Sullivan	158,975	175	525	52992
Sumner	172,262	189	569	57421
Tipton	63,865	70	211	21288
Trousdale	8,167	9	27	2722
Unicoi	18,376	20	61	6125
Union	19,301	21	64	6434

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Tennessee Total 6,523,686 7169 21,530 2174562 Total Target Market 2,203,261				
Wilson	124,073	136	409	41358
Williamson	202,923	223	670	67641
White	26,871	30	89	8957
Weakley	38,522	42	127	12841
Wayne	16,854	19	56	5618
Washington	130,586	144	431	43529
Warren	40,489	44	134	13496
Van Buren	5,450	- 6	18	1817

Item 4.b: although the reply states that no charity will be provided, please note that the applicant has budgeted \$1,000 in Year 1 and \$2,000 in Year 2 in the Projected Data Chart. Please explain.

IPM has budgeted \$1000 for year 1 and \$2000 in year 2 because although IPM does not provide charity care in general, IPM is anticipating the event of unforeseen circumstances in which non-payment occurs.

13. Section C, Need, Item 5

The applicant must address the utilization of all existing home health agencies in its proposed service area. A summary of the responses provided for the project specific criteria in Section C, Need, Item 1identifying the names of counties with a shortage of HHAs and the utilization of existing HHAs will suffice for this question.

Out of the 95 counties in the state of Tennessee, only 28 counties are covered by just one agency providing intrathecal home infusion services. This agency, Camellia, is licensed to provide services in the following 28 counties: Anderson, Blount, Bradley, Campbell, Claiborne, Cocke, Cumberland, Grainger, Grundy, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Knox, Loudon, Marion, McMinn, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, and Union. This leaves the remaining 67 counties within Tennessee without access to IPM's proposed services: Bedford, Benton, Bledsoe, Cannon, Carroll, Carter, Cheatham, Chester, Clay, Coffee, Crockett, Davidson, Decatur, Dekalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Greene, Hardeman, Hardin, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Johnson, Lake, Lauderdale, Lawrence, Lewis, Lincoln, McNairy, Macon, Madison, Marshall, Maury, Montgomery, Moore, Obion, Overton, Perry, Pickett, Putnam, Robertson, Rutherford, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Van Buren, Warren, Washington, Wayne, Weakley, White, Williamson, and Wilson. (Please reference Attachment 4. Section B, Project Description, Item ID. Camellia License Info for our source of counties serviced by Camellia and for a map of Camella's Tennessee county coverage.)

Please note that Camellia does not specialize in intrathecal home infusion services.

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14. Section C, Economic Feasibility, Item 4 (Projected Data Chart)

The revised table in the replacement application received on 7/28/14 is noted.

What accounts for the projected 17% increase in patient visits from Year 1?

Is this question number a typo? Is the actual question number 18? An increase in patient visits would be a direct response to an expected increase patient census.

20. Section C, Economic Feasibility, Item 9

The total Year 1 gross revenue amount identified in the table was \$139,150 in lieu of the \$288,000.00 amount entered in the Projected Data Chart. Please revise the table provided below to illustrate the projected revenues by payor source for Year 1 of the project.

The below chart was revised. This Projected Data Chart was previously submitted to reflect Net Revenues. We have adjusted them to reflect Gross Revenues.

Payor	Year One Gross Revenues	% of Total Revenues
Medicare	\$ 0. non covered service	0%
Medicaid/TennCare	\$ 0. Non covered service	0%
Commercial insurance	\$ 285,120.	99%
Self-Pay	\$2880.	1%
Charity	\$ 0. NA	0%
Total	\$288,000.	100%

21. Section C, Contribution to Orderly Development, Item 7.a.

The responses are noted. Please describe the organization and responsibilities of the applicant's governing body consistent with TDH licensure requirements set forth in TDH Rule 1200-08-26.

IPM's governing body will consist of a DON/Administrator who meets the criteria of TDH Rule 1200-08-26 of an HHA's administrator because she is an RN with over 9 years supervisory and administrative experience in home health care services.

26. Proof of Publication

The requested documentation of the publication in the newspapers listed in the table below was completed on Wednesday, July 30, 2014. Thank you

Newspaper	# TN Counties Included in Newspapers Coverage Area (as noted in copies of LOIs submitted to HSDA)
Tennessean	29
Commercial Appeal	14

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Paris Post Intelligencer	4
Daily News Journal	7
McMinnville General Standard	4
Buffalo River Review	3
Knoxville News Sentinel	17
Murfreesboro Daily News	5
Johnson City Press	7
Kingsport Times	6
Jackson Sun	5
Greenville Sun	3
Clarksville The Leaf Chronicle	The strate systems with a
Cookeville Herald Tribune	7
Dyersburg State Gazette	5
Chattanooga Free Times Press	16
Rogersville review	6
Bristol Herald Courier	6

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60th) day after written notification is September 23, 2014. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the <u>next review cycle</u>, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. → 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive

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Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please contact this office.

Sincerely,

Jeff Grimm HSD Examiner Enclosure

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Attachment 4.Section B.Project Description.Item 1.Pharmacy License



state of Tennessee

TENNESSEE BOARD OF PHARMACY
PHARMACY
INTRATHECAL COMPOUNDING SPECIALIST, LLC
206A JACOB'S RUN
SCOTT LA 70583

This is to certify that all requirements of the State of Tennessee

ID NUMBER: 0000004485 EXPIRATION DATE: 02/28/2016

CONTROLLED SUBSTANCE REGISTRATION

boundrie OHO

DCF171

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Attachment 4.Section B.Project Description.Item1.Pharmacy Contract

Pharmacy Service Agreement

This Pharmacy Services Ag	eement ("Agreement") is entered into	, ("Effective Date")
by and between Implanted	Pump Management, ("IPM") located at	200 Prosperity Place #102
Knoxville, TN 37923 and		, located a
	("CONTRACTO)R");

WHEREAS, CONTRACTOR is in the business of providing professional pharmacy services in jurisdictions where it is licensed;

WHEREAS, IPM is in the business of providing pharmacy and home infusion services to patients requiring intrathecal therapy in various jurisdictions;

WHEREAS, the parties desire that IPM shall use CONTRACTOR to all medication orders for patients of IPM when requested in jurisdictions where IPM is not licensed and/or requires assistance with said orders;

WHEREAS, the parties by this Agreement desire to set forth their various rights and responsibilities regarding the procedure and filling of medication orders;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties hereto agree as follows:

- 1. <u>TERM</u>. This agreement shall remain in full force and effect for an initial term of one year commencing on the Effective Date, and shall automatically be renewed unless either party delivers to the other party a written notice of intent to not to renew at least sixty (60) days prior to the end of each term, or any renewal thereof.
- 2. <u>TERMINATION</u>. This Agreement may be terminated with or without cause by either party at any time upon ninety (90) days prior written notice to the other party. The effective date of termination will be the first day of the month following the expiration of this ninety (90) day period.
- **3.** <u>REPRESENTATIONS</u>. Contractor hereby agrees to:
- a. Dispense certain prescription medication orders (collectively "Services") to and for the clients of IPM as requested and instructed by **only** IPM's clinical staff. Services shall include delivery to authorized representatives of the individual patient or the patient and consultation with the appropriate dispensing physician, patient and/or IPM clinical staff.
- b. Provide services and be available to IPM on a normal workweek based on Monday through Friday from 8:30 am to 7:00 pm EST and be available 24 hours a day, 7 days per week for consultation.
- c. Bill independently for all pharmacy services provided.
- d. Maintain at all times throughout the Term of this Agreement a valid policy of insurance covering professional liability arising from the acts, omissions or negligence of CONTRACTOR, its agents, employees, designees or sub-contractors in an amount no less

than One Million Dollars (\$1,000,000) per claim or occurrence and Three Million Dollars (\$3,000,000) aggregate per year and One Hundred Thousand (\$100,000) in property damage coverage. Said polices shall name IPM as an additional insured and shall provide that the insurance company will not cancel said policy of insurance without giving IPM thirty (30) days advance written notice. CONTRACTOR's insurance shall be primary. On or before the Effective Date of this Agreement, CONTRACTOR shall provide to IPM a copy of such policy or certificate of insurance, indicating that CONTRACTOR has liability coverage (in at least the minimum coverage amounts set forth above) including coverage for any acts of malpractice if CONTRACTOR is a licensed professional.

f. CONTRACTOR agrees to be in compliance with the following:

1. Has all required current local, state, and federal pharmacy licensure subject to no restrictions or limitations for each jurisdiction in which a medication order is received and filled by CONTRACTOR for an IPM patient.

2. Has no prior record of noncompliance with any state or federal agency or board regulating the distribution or dispensing of pharmaceuticals that would prevent the

operation of this Agreement.

3. For all staff performing services hereunder, current state licensure subject to no restrictions or limitations.

4. Performs services in accordance with current standards for pharmaceutical services as

promulgated by an accrediting organization approved by BHI.

5. Shall allow IPM to audit drug purchases for medications delivered to IPM patients and upon reasonable request provide documentation for drug purchases upon request.

4. <u>REPRESENTATIONS</u>. IPM agrees to provide records and information as is necessary for CONTRACTOR to dispense medications as requested by IPM ordering physicians and as permitted under applicable state and/or federal law, if any, and the rules and regulations promulgated there under and provides payment within sixty (60) days of the date of IPM's receipt of monthly billing statement.

5. JOINT REPRESENTATIONS. IPM and CONTRACTOR agree that:

- a. Nothing in this Agreement shall be used to constitute and obligation on the part of either party to make referrals to the other party. Further, nothing in this Agreement shall prohibit the parties from participating in health maintenance, insurance or third party payer programs as they so choose. This Agreement allows for the cost-effective use of resources and delivery of services and in no way constitutes a closed referral arrangement.
- b. The parties agree that each is at all times acting and performing as an independent contractor. Nothing in this Agreement shall be construed as creating a partnership, joint venture, or employment arrangement and no Party will have the power to obligate or bind the other Party in any manner whatsoever.
- c. Each party shall operate at all times in compliance with federal, state, and local laws, rules and regulations, the standards of Joint Commission (if applicable), and all currently

accepted methods and practices related to the provision of services contemplated hereunder.

- d. In order to facilitate the performance of this Agreement, each party may deem it necessary to disclose to the other certain proprietary and/or confidential information. Such information may include, without limitation, patient information, personnel information, financial information, market information, pricing information and service delivery information. Each party agrees to keep such information confidential. Each party agrees to maintain any information about the services provided by each party as propriety and confidential information and agree not to disseminate or disclose any information about the other to third parties.
- e. Any provisions of this Agreement creating obligations extending beyond the term of this Agreement will survive the expiration or termination of this Agreement, regardless of the reason of such termination.
- f. HIPAA To the extent applicable to this Agreement, the parties agree to comply with the applicable requirements of the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, as codified as 42 U.S.C.§1320d ("HIPAA") and any current and future regulations promulgated there under, including without limitation, the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Regulations"), the federal security standards as contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), and the federal standards for electronic transactions in 45 C.F.R. Parts 160 and 162 (the "Federal Transaction Standards") on or before their official compliance dates.
- g. All notices, consents or other communications which either party is required or may desire to give to the other under this Agreement shall be in writing and shall be given by personal delivery or by deposit, postage prepaid, in the United States mail, certified or registered mail, return receipt requested, addressed to the parties at their respective addresses set forth below:

If to CONTRACTOR:	Name:
	Address:
If to IPM:	Implanted Pump Management
	200 Prosperity Place #102 Knoxville, TN 37923

- h. This Agreement may be executed in several counterparts, each of which will be deemed an original, which together will constitute but one and the same Agreement.
- i. The validity, interpretation and performance of this Agreement will be governed

according to the laws of the State of New Jersey, without reference to its conflict of laws principles. All parties agree to and hereby submit to the jurisdiction of the Superior Court of the State of New Jersey, County of Bergen.

- j. Each party warrants that it has the right to enter into this Agreement. Performance of the Agreement will not violate any agreement between it and any other third party.
- k. Any amendments to this Agreement will be effective only if in writing and signed by both parties. This Agreement constitutes the entire agreement of the parties hereto and supersedes all prior or contemporaneous agreements, undertakings and understanding of the parties in connection with the subject matter hereof.
- 1. No waiver of a breach of any provision of this Agreement will be construed to be a waiver of any other breach of this Agreement, whether of a similar or dissimilar nature.
- 6. NON COMPETITION OF INFUSION SERVICES. During the term of this Agreement and for a minimum period of three (3) years after termination of this Agreement or any additional period of time that protects the interests of IPM that is allowed by law, CONTRACTOR specifically agrees not to perform any such business IPM performs including, but not limited to any monitoring of patients, home care, and/or nursing services related to implanted pump therapies. Notwithstanding the foregoing, nothing in this provision shall be interpreted to restrict CONTRACTOR at any time from the filling of implanted pump therapy prescriptions in any way, with the exception of providing services to another homecare entity. It shall be deemed a breach of this provision if any patients serviced by IPM for implanted pump therapies during the term of this Agreement are subsequently serviced by another provider that is affiliated in any way with CONTRACTOR or its employees, directors, partners, owners or agents, directly or indirectly. If ownership of IPM is transferred or if IPM sells all or substantially all of its assets then this provision and full agreement will be transferable to the new entity. Further, CONTRACTOR agrees that during the term of this Agreement and for a period of five (5) years after termination of this Agreement or any such cessation of this agreement or employment for whatever reason, CONTRACTOR shall not solicit any employee of IPM during the term of this Agreement to enter into any employment agreement or independent contract arrangement with Contractor
- 7. **EXCLUSIVITY**. a. For so long as CONTRACTOR is capable of dispensing medication for IT therapy to certain patients of IPM, IPM agrees to provide all medication orders for the specific patients that are enrolled in the homecare program with IPM residing in States where CONTRACTOR is licensed unless IPM decides to fill patient prescriptions itself or in those jurisdictions that IPM receives referrals that request and/or are from pharmacies or physicians that require the pharmacy services to be used by another or currently used entity for that patient. IPM is not restricted in the performing pharmacy services in any manner during this Agreement and upon termination of this Agreement.
- b. Upon the commencement and through the term of this agreement, CONTRACTOR agrees that IPM shall be the exclusive home infusion provider that will be referred or recommended to patients, referral sources and/or physicians.

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SUPPLEMENTAL #2
August 18, 2014

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8. JOINT DISASTER RECOVERY. Both parties agree to act as back-up pharmacy sites for each other in the event that one party experiences a Disaster situation. Both parties hereby agree to sign or contact governmental or quasi-governmental agency, any accreditation companies or entities to evidence such an agreement between the parties. In the event that one party requires emergency services as a result of a disaster whether a result of natural causes or other inability to function, the other party hereby agrees to reasonably perform and service the patients of the other at a cost to be mutually agreed upon.

In Witness whereof, we the undersigned, duly authorized representatives of the parties to this Agreement, hereinabove expressed, have entered into this Agreement without reservation and have read terms herein.

Dated:	By:
	(Print Name and Title)
	Implanted Pump Management
Dated:	By:
	(Print Name and Title)
	CONTRACTOR:

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Attachment 4.Section B.Project Description.Item1.Pharmacy Letter



July 31, 2014

To Whom It May Concern:

Intrathecal Compounding Specialists (ICS) would like to formally express interest in contracting with a home infusion nursing provider in order to provide compounded medication to patients in need within the state of Tennessee. We currently hold all applicable valid pharmacy licensure that indicates our ability to provide such services sufficiently.

Regards,

Stuart H. Burgess, R.Ph.
Director of Pharmacy

206-A Jacob's Run Scott, LA 70583

Tel 337.237.6077 Fax 337.237.8841 Toll 877.334.5548

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Attachment 4.Section B.Project Description.Item 1.Pharmacy Brochure





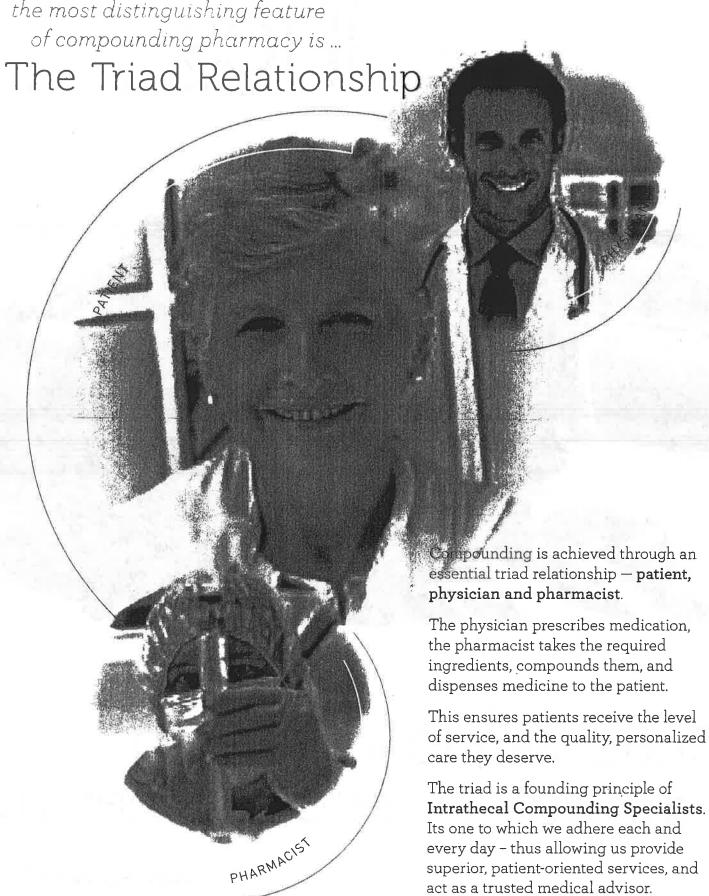
Dedicated to improving the outcomes of IT Therapy

icspharmacy.com

every day - thus allowing us provide superior, patient-oriented services, and

act as a trusted medical advisor.

the most distinguishing feature



Experienced Personnel & Quality Processes

ICS understands the business and operations of a clinic, and we know how to offer solutions that make managing IT Therapy more clinically, logistically and economically viable.

Our pharmacists are highly trained, and available for consultation about any aspect of the preparation, ordering and delivery of our medications.

The stringent systems we've put in place assure patient safety and quality control checks throughout the entire process, which includes:

- + All powders are from FDA registered facilities
- + All preparations include a certificate of analysis
- + All preparations tested for endotoxins, sterility, pH, potency, and particulate matter by an independent lab
- + Automated technology integrated with lab processes to prevent human error
- + Exceeds levels set by USP <797> for highest levels (Risk Level III compounds)
- + PCAB Accredited™ (equivalent to board certification)

All Medications Prepared In Our Top Tier Facility

We built ICS from the ground up, and we put a priority on designing a facility with the most sophisticated and advanced technology available to the industry.

All preparations are made in our state-licensed facility, which houses an impressive ISO 7 Class 10,000 clean room. The clean room is regulated for air quality, humidity, and temperature control. It features Laminar flow hoods, positive pressure controlled compounding rooms, HEPA filtration, and air exchanges at a rate of 60-90x/per hour.

The mission of ICS is to increase patient access to intrathecal drug therapy by assuring better clinical outcomes and creating a favorable environment to support physician interests.

ICS Provides Ancillary Services

ICS is a name you can trust. Intrathecal medications are our specialty, and serving you as a business partner is our focus. We are licensed across the United States, and we offer a wide range of ancillary services to help you run a more efficient practice.

In the current healthcare environment, we've seen reimbursements decrease, payment denials increase, operational costs increase, and the costs of defensive medicine skyrocket due to litigation and a steady rise in malpractice premiums.

ICS provides ancillary services to help you achieve financial success with your IT therapy patients.

Services include:

- + Back office support for claim submission & EOB analysis
- + Customized financial reports (refill analysis)
- + Off site pump management service (home, hospital, nursing home, rehab facility)
- + Outsourced billing
- + A seamless ordering process
- + Hassle free transition to ICS
- + Order verifications
- + FedEx Priority Alert™ Delivery (meets critical needs for healthcare shipments)
- + Clinical consultation on polyanalgesia
- + Assistance with the clinic's refill schedule
- + On-call pharmacists (24/7)



206-A Jacob's Run Scott, LA 70583

tel: 877 334 5548 fax: 877 334 5549

icspharmacy.com

Intrathecal Compounding Specialists was created with one unique focus - intrathecal preparations: ICS matches a phracal commitment to this ICS is a compounding pharmacy that is for solely on improving the efficacy of intrathecal preparations. ICS combines expert pharmacological knowledge with business acumen in practice management to help physicians improve patient access to IT Therapy.

Our sole focus on IT medications and commitment to quality patient outcomes puts ICS at the top of this sub specialty of pharmacy.

We deliver the highest quality preparations, and provide physicians, medical staff and patients with seamless access throughout the process.

ICS articulates reimbursement needs, and helps you run a more efficient practice.

Quality Preparations, Fully Qualified

All major medical decisions are qualified. Don't you think its time your pharmacy is, too?

All preparations are not created equal, and one size does not fit all. Never have these statements been more applicable than to the integrity of intrathecal preparations. But, until now, quality guarantees have been lacking.

ICS is leading a charge within the industry to make qualified preparations a standard of care. We provide these assurances because we know integrity of the preparations is vital to improving patient outcomes, and it can be critical to achieving operational success.

IT refills are our sole focus. Integrity in our preparations drives that focus. It also serves as the foundation of our business philosophy.

An Impact on your Bottom Line

It starts with assurances, peace of mind, and improved patient access that results from high-quality practices and qualified meds. Bring ICS to your team, and you'll see an increase in cash flow, a reduction in procedural costs, and improvement in the claims process.

Why? Quite simply – better meds and better practices leads to better patient outcomes. The time, hassle, and cost associated with marginal outcomes, titrations, the addition of adjuvant medications, dye studies, rotor studies, and surgical explorations would become less prevalent with pre-qualified medications. In fact, clinical risks associated with IT therapy, such as inflammatory mass, may decline once we adopt the use of prequalified preparations as the standard of care.

All Pharmacies Not Created Equal

ICS operates at the highest levels of compliance. Since our founding, we've surpassed USP Chapter <797>. But, more importantly, we've earned PCAB Accreditation. PCAB is to compounding pharmacies what ABMS Certification is to physician specialties. It's a process that signals our commitment and expertise to helping you achieve superior patient outcomes. We encourage you to speak with your current provider of high-risk sterile preparations and put them to the challenge:

Is your pharmacy PCAB Accredited? ICS is because we think its the best indicator of knowledge, experience and skills in this specialized field of pharmacy.

PCAB Accreditation is an even more comprehensive way to ensure your compounding pharmacy has undergone the profession's most rigorous review and inspection measures. ICS Pharmacy is PCAB Accredited.™

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SUPPLEMENTAL #2
August 18, 2014
12:30 pm

Attachment 6.Project Description.Item IIA

CARE COORDINATION CONTRACT

August 18, 2014

This Agreement made this _____day of _ 2013, between Implanted Pump Management, LLC with office located at 200 Prosperity Place #102, Knoxville, TN 37923, referred to as "IPM" and located at _____, referred to as "Referral Source".

Recitals

- A. IPM or its affiliates, contractors and/or agents, is licensed to perform nursing and pharmacy duties in the jurisdiction of the Referral Source and/or its patients.
- B. IPM and the Referral Source are fully insured to perform their respective services set forth herein.
- C. The Referral Source desires to refer certain patients in need of infusion therapy and monitoring for an intrathecal implanted pump.

The parties hereby agree to the following:

1. SERVICES

IPM will be responsible for refilling, titration and monitoring of the intrathecal pump patients. IPM will supply the nursing services associated with home infusion therapy. IPM will handle all issues associated with the pump and field all patient calls. The patient will be directed to call IPM when in need of dose titration or any other issues related to infusion therapy. IPM will coordinate all refill dates with the patient and schedule accordingly with the Referral Source. All reports, nursing notes and telemetry results will be accessible to the prescribing physician via WebPortal after each visit for review. IPM is able to go to the patient's home, school, work, hospital, nursing facility or other location to refill the pump.

Referred patients are billed through insurance procedures obtained at admission with IPM and will not be billed through the Referral Source. The Referral Source is a Third Party and not part of IPM's billing process. Such billing is processed through IPM.

2. NO PAYMENT FOR REFERRAL

It is specifically agreed to by IPM and the Referral Source that this Agreement does not allow for remuneration of any kind for any patient referrals. No monetary, as well as other payments have or will be exchanged for referrals as contemplated by the parties. Payments such as kick-backs in any form are prohibited by any person directly or indirectly from each party.

3. NO PRIOR AGREEMENT

This Agreement embodies the entire understanding between the Parties relating to the subject of this Agreement, and there are no related prior representations or agreements not specified herein.

4. NO CHANGES

No change in this Agreement will be binding on either Party unless approved in writing by its authorized representative.

5. ENFORCEABILITY

If any provision of this Agreement is determined to be invalid, illegal or unenforceable for any reason, that provision will be reformed to the maximum extent permitted to preserve the Parties' original intent, failing which, it will be severed from this Agreement with the balance of the Agreement continuing in full force and effect. Such occurrence will not have the effect of rendering the provision in question invalid in any other jurisdiction or in any other case or circumstances, or of rendering invalid any other provisions constrained in this Agreement to the extent that such other provisions are not themselves actually in conflict with any applicable law.

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6. TERMINATION

Either party may terminate with or without cause this Agreement at any time upon ninety (90) days prior written notice to the other party. The effective date of termination will be the first day of the month following the expiration of this ninety (90) day period. This Agreement may automatically renew upon the expiration of the Agreement.

7. INSURANCE

IPM shall maintain general and professional liability insurance with a limit of not less than \$1,000,000 per occurrence and \$3,000,000 in the aggregate, and shall supply the Referral Source with a certificate of insurance evidencing such coverage and shall provide thirty (30) days' written notice prior to the cancellation of any such policies.

8. ASSIGNMENT

Neither party may assign its rights or obligations with respect to this Agreement without the prior written approval of the other party; provided, however, that such an assignment may be made to an entity which is related by virtue of a common parent corporation or which is directly or indirectly, wholly owned or controlled by the same entity as the assigning party.

9. INDEMNIFICATION

Each party agrees to indemnify the other, their affiliates and their respective officers, directors, employees and agents against, and hold the same harmless from, all liability, losses, damages, obligations, judgments, claims, causes of action and expenses associated therewith (including settlements, judgments court costs and attorney's fees) resulting from or arising out of, directly or indirectly, and, any negligent or intentional act or omission or any failure to perform any obligation undertaken in or any covenant made under this Agreement. Upon notice, each party shall resist and defend at its own expense, and by counsel reasonably satisfactory to the other, any such claim or action.

IPM agrees to indemnify and hold the Referral Source harmless against and from any and all claims of the patients that arise from the infusion, programming or care provided by IPM, its affiliates, contractors and/or agents. IPM will be responsible for infusion and monitoring as set forth above. The Referral Source and/or the physicians providing the prescription are solely responsible for medication errors not related to IPM-provided infusion therapies. The Referral Source and/or the physicians agrees to indemnify and hold IPM harmless against and from any and all claims of the patients that arise from the incorrect prescription or any such medication order and/or prescription error not related to IPM-provided infusion therapies.

10. INDEPENDENT CONTRACTOR

The parties agree that each is at all times acting and performing as an independent contractor. Nothing in this Agreement shall be construed as creating a partnership, joint venture, or employment arrangement and no Party will have the power to obligate or bind the other Party in any manner whatsoever. Each party may contract/subcontract with multiple providers or agencies at anytime.

11. EQUAL EMPLOYMENT OPPORTUNITY POLICY

The parties agree, if applicable, to comply with the Equal Employment Opportunity policies provided in Executive Order 11246 (as set forth in 41 CFR § 60-1.4(a) and incorporated herein by reference), the Rehabilitation Act of 1973 (as set forth in 41 CFR § 60-741.5(a) and incorporated herein by reference), and the Vietnam Era Veterans Readjustment Assistance Act (as set forth in 41 CFR § 60-250.4 and incorporated herein by reference).

12. LICENSURE AND CERTIFICATION

Each party shall operate at all times in compliance with federal, state, and local laws, rules and regulations, the standards of Joint Commission (if applicable), and all currently accepted methods and practices related to the provision of services contemplated hereunder.

13. CONFIDENTIALITY AND NON-SOLICITATION

In order to facilitate the performance of this Agreement, each party may deem it necessary to disclose to the other certain proprietary and/or confidential information. Such information may include,

without limitation, patient information, personnel information, financial information information, financial information, patient information, personnel information, financial information, personnel information, financial information, personnel informa pricing information and service delivery information. Each party agrees to keep such information confidential. Each party agrees to maintain any information about the services provided by each party as propriety and confidential information and agree not to disseminate or disclose any information about the other to third parties.

During the term of this agreement and for a period of five (5) years thereafter the Referral Source will not in conjunction with any other person, firm or entity solicit, entice or attempt to solicit or entice or employ any person that is or was employed with IPM.

Referral Source will not on behalf of or in conjunction with any other person, firm or entity, to solicit, entice or attempt to solicit or entice any principal or owner of IPM to sever or alter its/his relationship with IPM to the detriment of IPM.

14. SURVIVAL

Any provisions of this Agreement creating obligations extending beyond the term of this Agreement will survive the expiration or termination of this Agreement, regardless of the reason of such termination.

15. HIPAA

To the extent applicable to this Agreement, the parties agree to comply with the applicable requirements of the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, as codified as 42 U.S.C.§1320d ("HIPAA") and any current and future regulations promulgated thereunder, including without limitation, the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Regulations"), the federal security standards as contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), and the federal standards for electronic transactions in 45 C.F.R. Parts 160 and 162 (the "Federal Transaction Standards") on or before their official compliance dates. The parties agree not to use or further disclose any protected health information, as defined in 45 C.F.R. §164.501, or individually identifiable health information, as defined in 42 U.S.C. § 1320(d) (collectively, the "Protected Health Information"), concerning a patient other than as permitted by this Agreement, the requirements of HIPAA, and the regulations promulgated under HIPAA including, without limitation, the Federal Privacy Regulations, the Federal Security Regulations, and the Federal Transaction Standards. Additionally, on or before the official date of compliance, shall enter into a mutually agreeable business associate agreement with Referral Source, if required under the Federal Privacy Regulations agreeing to safeguard Protected Health Information, and upon its execution, such agreement shall be attached to this Agreement and incorporated herein as an addendum. IPM will fully adhere to the requirements under HIPAA procedure and will have all referred patients sign the proper HIPAA disclosure/consent forms at the admission of treatment and such is a permanent part of the patient's medical chart.

16. ELECTRONIC STORAGE OF AGREEMENT

The parties agree that the original of the Agreement, including the signature pages, may be scanned and stored in a computer database or similar device, and that any printout or other output which is readable, and which is shown to be an accurate reproduction of the original of this document, may be used for any purpose just as if it were the original Agreement, including the proof of the content of the original writing and the signing of the original writing.

17. NOTICES

All notices, consents or other communications which either party is required or may desire to give to the other under this Agreement shall be in writing and shall be given by personal delivery or by deposit, postage prepaid, in the United States mail, certified or registered mail, return receipt requested, addressed to the parties at their respective addresses set forth below:

If to Referral Source:

August 18, 2014 12:30 pm

If to IPM:

Implanted Pump Management 200 Prosperity Place #102 Knoxville, TN 37923

18. GENERAL PROVISIONS

This Agreement may be executed in several counterparts, each of which will be deemed an

original, which together will constitute but one and the same Agreement.

The validity, interpretation and performance of this Agreement will be governed according to the laws of the State of Tennessee, without reference to its conflict of laws principles. All parties agree to and hereby submit to the jurisdiction of the Superior Court of the State of Tennessee, County of Knox.

Each party warrants that it has the right to enter into this Agreement.

Performance of the Agreement will not violate any agreement between it and any third party.

Corporation warrants that it owns the Corporation represented in this Agreement and that the execution of this Agreement does not violate any other agreement or understanding by which Corporation is bound. Corporation further warrants that it is unaware of any information that would render any of the claims of its Confidential Information invalid or unenforceable.

Corporation further warrants that, to the best of its knowledge, there is no third party ownership claims to the Corporation and that Corporation has taken all measures to have employees and contractors assign such intellectual property rights to Corporation.

Contracting parties must be clearly identified by using the contracting party's full legal name and

state of legal incorporation or registration.

Any amendments to this Agreement will be effective only if in writing and signed by both parties.

This Agreement constitutes the entire agreement of the parties hereto and supersedes all prior or contemporaneous agreements, undertakings and understanding of the parties in connection with the subject matter hereof.

No waiver of a breach of any provision of this Agreement will be construed to be a waiver of any other breach of this Agreement, whether of a similar or dissimilar nature.

Dated:	Ву:
Dated:	By:
	Melissa Hess, Director of Nursing

SUPPLEMENTAL #2
August 18, 2014
12:30 pm

Attachment 8. Section C.Need.Item 1A.US Census Quickfacts

August 18, 2014

Search 12:30 pm

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Topics
Population, Economy

Geography Maps, Geographic Data Library Infographics, Publications Data Tools, Developers About the Bureau Research, Surveys Newsroom News, Events, Blogs

State & County QuickFacts

Tennessee

People QuickFacts	Tennessee	246 420 020
Population, 2013 estimate		316,128,839
Population, 2010 (April 1) estimates base		308,747,716
Population, percent change, April 1, 2010 to July 1, 2013	2.4%	2.4%
Population, 2010		308,745,538
Persons under 5 years, percent, 2013	6.2%	6.3%
Persons under 18 years, percent, 2013	23.0%	23.3% 14.1%
Persons 65 years and over, percent, 2013	14.7% 51.2%	50.8%
Female persons, percent, 2013	31.270	30.070
White alone, percent, 2013 (a)	79.1%	77.7%
Black or African American alone, percent, 2013 (a)	17.0%	and the second second
American Indian and Alaska Native alone, percent, 2013 (a)	0.4%	1.2%
Asian alone, percent, 2013 (a)	1.6%	5.3%
Native Hawaiian and Other Pacific Islander alone, percent, 2013 (a)	0.1%	0.2%
Two or More Races, percent, 2013	1.7%	2.4%
Hispanic or Latino, percent, 2013 (b)	4.9%	17.1%
White alone, not Hispanic or Latino, percent, 2013	74.9%	62.6%
Living in same house 1 year & over, percent, 2008-2012	84.4%	84.8%
Foreign born persons, percent, 2008-2012	4.5%	12.9%
Language other than English spoken at home, pct age 5+, 2008-2012	6.6%	20.5%
High school graduate or higher, percent of persons age 25+, 2008-2012	83.9%	85.7%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	23.5%	28.5%
Veterans, 2008-2012	493,980	21,853,91
Mean travel time to work (minutes), workers age 16+, 2008-2012	24.1	25.4
Housing units, 2013	2,840,914	132,802,85
Homeownership rate, 2008-2012	68.4%	65.5%
Housing units in multi-unit structures, percent, 2008-2012	18.2%	25.9%
Median value of owner-occupied housing units, 2008-2012	\$138,700	\$181,40
Households, 2008-2012	2,468,841	115,226,80
Persons per household, 2008-2012	2.51	2.6
Per capita money income in past 12 months (2012 dollars), 2008-2012	\$24,294	\$28,05
Median household income, 2008-2012	\$44,140	\$53,04
Persons below poverty level, percent, 2008-2012	17.3%	
Business QuickFacts	Tennessee	USA
Private nonfarm establishments, 2012	130,592 ¹	7,431,80
Private nonfarm employment, 2012	2,344,047 ¹	115,938,46
Private nonfarm employment, percent change, 2011-2012	1.9%	2.29
the state of the s	471,026	22,735,91
Nonemployer establishments, 2012		
Total number of firms, 2007	545,348	27,092,90
Black-owned firms, percent, 2007	8.4%	7.19
American Indian- and Alaska Native-owned firms, percent, 2007	0.5%	0.9%

Asian-owned firms, percent, 2007 Native Hawaiian and Other Pacific Islander-owned firms.	2.0%	252 ^{5.7%}
percent, 2007	0.1%	0.1%
Hispanic-owned firms, percent, 2007	1.6%	8.3%
Women-owned firms, percent, 2007	25.9%	28.8%
Manufacturers shipments, 2007 (\$1000)	140,447,760	5,319,456,312
Merchant wholesaler sales, 2007 (\$1000)	80,116,528	4,174,286,516
Retail sales, 2007 (\$1000)	77,547,291	3,917,663,456
Retail sales per capita, 2007	\$12,563	\$12,990
Accommodation and food services sales, 2007 (\$1000)	10,626,759	613,795,732
Building permits, 2012	20,147	829,658
Geography QuickFacts	Tennessee	USA
Land area in square miles, 2010	41,234.90	3,531,905.43
Persons per square mile, 2010	153.9	87.4
FIPS Code	47	

1: Includes data not distributed by county.

- (a) includes persons reporting only one race.
- (b) Hispanics may be of any race, so also are included in applicable race categories.
- D: Suppressed to avoid disclosure of confidential information
- F: Few er than 25 firms
- FN: Footnote on this item for this area in place of data
- NA: Not available
- S: Suppressed; does not meet publication standards
- X: Not applicable
- Z: Value greater than zero but less than half unit of measure shown

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits Last Revised: Tuesday, 08-Jul-2014 06:37:34 EDT

ABOUT US

FIND DATA

BUSINESS & INDUSTRY

PEOPLE & HOUSEHOLDS

SPECIAL TOPICS

NEWSROOM

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SUPPLEMENTAL #2

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Attachment 8. Section C.Need.Item 1A.2013 Final JAR

SUPPLEMENTAL #2

Joint Annual Report of Home Health Agencies - 2016 Tigns * 18, 2014

Comparison of Population Based Need Projection vs. Actual Utiliz * 2006 (2018 vs. 2013)**

	Agencies	Agencies	Total			國憲法制設			Need or
Service Area	Licensed to Serve	Report Serving	Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	(Surplus) for 2018
Tennessee	1,619	1.457	175,924	6,528,014	of the local division in the Real Property lies.	A STATE OF THE PARTY OF THE PAR	A STATE OF THE PARTY OF THE PAR	AND DESCRIPTION OF THE PARTY OF	(81,654
Anderson	22	19	2,893	76,182			2,956		(1,789
Bedford	20	19	1,120	46,700					(454
Benton	11	10	667	16,315					(417
Bledsoe	10	8	462	12,698					(269)
Blount	18	18	2,507	126,809					(645)
Bradley	16	14	2,021	102,235			2,125		(512)
Campbell	21	18	1,715	41,163					(1,135
Cannon	19	16	423	14,013		14,540			(221
Carroll	13	13	1,246	28,213		27,831	1,229		(812)
Carter	12	11	2,072	57,228		57,680		865	(1,223)
Cheatham	24	25	772	39,603				611	(183)
Chester	14	13	563	17,355		17,999		270	(314)
Claiborne	19	15	2,002	32,457	0.0524	33,280		499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673		115	(133)
Cocke	16	14	1,467	36,330	0.0324	38,615		579	(980)
Coffee	20	16	1,407	53,784	0.0404	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0348	14,683	541	220	(321)
Cumberland	15	13	1,601	57,370	0.0309	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0279	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0230	12,080	655	10,235	(473)
DeKalb	21	16	469	18,918	0.0342	12,000 19,125	474	287	(473)
Dickson	25	24	1,617	50,596	0.0240	51,964	1,661	779	(881)
Dyer	11	10	1,671	38,205	0.0320	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0437	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0336	42,122	1,459	632	(828)
Gibson	15	14	1,924	50,748	0.0379	52,163	1,978	782	(1,195)
Giles	12	11	1,001	29,325	0.0341	29,285	1,000	439	(560)
Grainger	22	20	886	22,994	0.0385	23,675	912	355	(557)
Greene	20	17	2,454	69,888	0.0351	71,594	2,514	1,074	(1,440)
Grundy	18	16	529	13,396	0.0395	13,293	525	199	(326)
Hamblen	19	17	2,835	63,763		65,570	2,915		(1,932)
Hamilton	16	16	8,038	345,447	0.0233	353,577	8,227	5,304	(2,924)
Hancock	14	11	682	6,652	0.1025	6,640	681	100	(581)
Hardeman	17	15	917	26,492	0.0346	26,067	902	391	(511)
Hardin	16	14	1,157	25,968	0.0446	26,244	1,169	394	(776)
Hawkins	21	18	2,148	57,273	0.0375	58,164	2,181	872	(1,309)
Haywood	15	13	612	18,199	0.0376	18,009	606	270	(335)
Henderson	14	13	1,015	28,080	0.0350	28,631	1,035	429	(605)
Henry	10	10	1,283	32,595	0.0394	32,956	1,297	494	(803)
Hickman	18	17	725	24,393	0.0394	24,698	734	370	(364)
Houston	12	11	281	8,358	0.0297	8,447	284	127	(157)
Humphreys	16	14	803	18,488	0.0330	18,561	806	278	(528)
Jackson	12	11	402	11,355	0.0354	11,495	407	172	(235)
Jefferson	20	19	1,749	53,006	0.0334	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
Lake	6	5	325	9,795	0.0223	9,468	314	142	(172)
EAL/O	<u> </u>	<u> </u>	323	9,190	0.0002	3,400	314	144]	(172)

Joint Annual Report of Home Health Agencies - 2014 Gust* 18, 2014 Comparison of Population Based Need Projection vs. Actual Utiliz 1200 (2018 vs. 2013)**

Service :	Agencies Licensed to	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need 2 (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Lauderdale	Serve 14	11	857	27,465	0.0312	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0394	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0332	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0313	35,697	1,116	535	(580)
Loudon	23	21	1,572	50,356	0.0312	53,192	1,661	798	(863)
McMinn	17	17	1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315	101,001	3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256	28,992	743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomery	19	20	2,903	184,087	0.0158	200,561	3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216	22,004	476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	(141)
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256	16,588	425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)
Stewart	10	10	339	13,436	0.0252	13,941	352		(143)
Sullivan	14	13	5,259	158,451	0.0332	161,136			(2,931)
Sumner	26	27	4,160	169,409	0.0246	183,406		2,751	(1,753)
Tipton	26	22	1,298	63,001	0.0206	67,545		1,013	(378)
Trousdale	16	14	431	8,046	0.0536		460		(331)
Unicoi	13	11	659	18,334	0.0359		665		(388)
Union	21	18	371	19,231	0.0193				(84)
Van Buren	12	11	240	5,456	0.0440			82	(159)
Warren	20	15	2,266	40,299	0.0562	41,155		617	(1,697)
Washington	16	14	4,181	128,537	0.0325	138,370		2,076	(2,425)
Wayne	11	9	640	16,887	0.0379			251	(383)
Weakley	13	11	1,180	38,255	0.0308	39,491	1,218		(626)
White	14	9	962	26,612	0.0361	27,974		420	(592)
Williamson	32	32	2,815	198,045	0.0142	223,333			
Wilson	28	31	3,727	121,626	0.0306 Ith Agencies	133,357	4,086	2,000	(2,086)

*Most recent year of Joint Annual Report data for Home Health Agencies

^{**}Data is projected four years from the year the Home Health data was finalized, not the actual year of Home Health data.

August 18, 2014 12:30 pm

Attachment 9.Section C.Need.Item 1A

SUPPLEMENTAL #2 **August 18, 2014**

12:30 pm

July 24, 2014

To Whom It May Concern:

This letter is written in regards to the need for more home intrathecal infusion services in the state of Tennessee.

I have an implanted intrathecal pump and a homecare option is definitely the best for me and my family.

Please consider allowing more companies to introduce intrathecal home management services to better serve the individuals of Tennessee.

Sincerely,

Bom Flent

Bonnie Flint 120 Brookwood Lane Apt 20 Gainesboro, TN 38562

August 18, 2014 12:30 pm

July 24, 2014

To Whom It May Concern:

This letter is written in regards to the need for more home intrathecal infusion services in the state of Tennessee.

I have an implanted intrathecal pump and a homecare option is definitely the best for me and my family.

Please consider allowing more companies to introduce intrathecal home management services to better serve the individuals of Tennessee.

Margaret Stacey
6610 SE Tater Pecler Rd
Lebanon, TN 37090

August 18, 2014 12:30 pm

Attachment 9.Section C.Need.Item 1C

August 18, 2014 12:30 pm

To Who it may concern,

I am writing this letter to request consideration for allowing for an increase in specialized implanted pump home care services in the state of Tennessee. This service is needed to assist in refilling and managing implanted Intrathecal pumps in patients with spasticity and pain that have failed traditional pain and spasticity treatment modalities. It has been my experience that it is difficult to assist physicians in finding qualified home care services capable of handling implanted pump refills and management. Many physicians have expressed that past attempts with "non-pump specialized" home care services have produced discouraging results. They have expressed that a lack of refill skill, pump mechanical understanding and ability to coordinate pump management as reasons to not use existing home care options.

Care and management of these devices require detailed, skilled professional services that are best handled by Home professionals trained and focused on the specific task of pump refill and management in order to maximize patient outcomes and safety. Many patients in this population have great difficulty making it to a facility to have their pump managed post implant. This exposes patients to safety risks when appointments are missed. Many patients require the assistance of ambulance and other intensive transfer methods in order to keep refill appointments.

Offering an increase in specialized intrathecal pump home care management services will allow for improved quality of life in the spasticity and pain pump patient population. Implant numbers continue to increase and with it, the need for care, refills and education from Intrathecal home care services.

Please let me know if I can answer any questions.

Sincerely,

Denny Castillo Smokey Mountains District Medtronic Neurological 261

SUPPLEMENTAL #2

August 18, 2014 12:30 pm

Attachment 12.Section C.Need.Item 4A.TennCare Data

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August 18, 2014 12:30 pm

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SUPPLEMENTAL #2 August 18, 2014 12:30 pm

AFFIDAVIT

STATE OF NEW TERSEL

COUNTY OF BERGEN

being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, et seq., and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

Sworn to and subscribed before me this 4 day of (Month)

Public in and for the County/State of NEW TERSEY

NOTARY PUBLIC

My commission expires

12 - 29 (Month/Day)

2016 (Year)

NADIA SALMON Notary Public New Jersey My Commission Expires 12-29-16

a Notary



9:44 am



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364/Fax:615/532-9940

August 28, 2014

Melissa Hess, RN Director of Nursing Implanted Pump Management 200 Prosperity Place #102 Knoxville, TN 37923

RE: Certificate of Need Application CN1407-027

Implanted Pump Management

Dear Ms. Hess,

This will acknowledge our August 18, 2014 receipt of your supplemental response pertaining to your application for a Certificate of Need for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services to patients residing in all 95 Tennessee counties from its parent office located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Towards the end of this letter you will find information regarding "deemed complete" or "deemed incomplete" status of an application and a "deemed void" date. If this application is not complete prior to that date, it will be deemed void. In order to help expedite the review process, please resubmit all required information in the format described and respond to our initial questions in triplicate, with affidavit by 1:00 p.m. August 29, 2014. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section A, Applicant Profile, Item 13 (Medicare/Tenncare coverage)

The response is noted. Please document non-coverage by these parties using references such as excerpts of laws, statutes, rules, bulletins, or related correspondence from CMS and/or related parties. This would be helpful to

August 29, 2014 9:44 am

confirm since some coverage by Medicare appears to be available for implanted pump infusion management for individuals with cancer pain.

Since IPM is not a Medicare certified agency, Medicare plans will not reimburse IPM for services provided to Medicare recipients. Medicare only covers services done by Medicare Certified Agencies.

2. Section B, Project Description, Item 1

Item G: Given the existing Camellia Home Health Agency of East Tennessee's licensed coverage of Cocke County, why does the applicant feel it necessary to base an RN out Newport?

The base locations for our nurses were chosen with intention of providing comprehensive statewide coverage of services. The fact that a single home health agency in the state – Camellia Home Health Agency – includes intrathecal home infusion therapy within their expansive repertoire of services does not factor into our goal of providing intrathecal pump patients across the state with access to our highly specialized care. We anticipate receiving referrals for patients regardless of whether they are within Camellia's geographic service area due to their disease states requiring the specific specialization of services that we will provide.

Cocke County was specifically chosen as the agency office site due to its centralized location within the state. Again, the fact that Camellia also has an office location within this county has no bearing on our company regarding our provision of services and vice versa due to our dissimilar structure and IPM's specialization of services.

Item I: Please explain how the Administrator/RN Director of Nurses is going to respond to on call situations in the 20 minute response time noted while also providing skilled nursing care services to patients in their homes.

Our Administrator/RN Director of Nursing will respond to <u>all</u> on call and emergency situations within 20 minutes via phone service for the requisite assessment and triaging. As our specialized services successfully negate a vast majority of inpatient and hospital emergency room and physician services, this is an appropriate and highly effective response time and manner.

Item J: Please summarize what is involved in the required pump manufacturer training curriculum. A copy of a course outline or similar reference may be helpful in this regard. Please explain education and training that is necessary to respond to emergency situations such as an overdose situation.

The training for an IPM RN consists of two days of theory, mechanics, and medications utilized for the therapy. The second phase of training focuses on the programmer (device used to program the pump) and the refill procedure done in a classroom setting. The next phase is clinical practice with the refill and programming through required programming tests and successful demonstration of pump refill techniques through utilizing a "dummy" patient. At this point in the training the IPM RN would be able to observe home visits. The IPM RN in training will work with an IPM RN licensed in the state of Tennessee for practical and clinical experience and proficiency. The training RN must demonstrate accurate knowledge of the pump system, all components and steps for programming and refill at least three times

Melissa Hess August 28, 2014 Page 3

August 29, 2014 9:44 am

supervised for every level of pump. IPM grades each pump from 1 to 3 based on difficulty level of palpation, identification of borders, and refill procedure. Please see attached documentation (Attachment 2.Section B.Project Description.Item 1.Item J) for training.

3. Section B, Project Description, Item II.C. The response is noted. The attached graph appears to be an excerpt of a bar chart showing the results of a study over a 4 year period regarding complication rates after intrathecal catheter and pump placement in pediatric patients (Pain Physician Journal, 2012). The authors are two physicians at the Department of Anesthesiology, University of Virginia. It is unclear how this medical research supports the applicant's whole patient approach leading to a 50% reduction in ED visits. Please explain.

Note: as a general request for clarification, review of page 8 of the 1st supplemental response described potential patient care enhancements. Please clarify why the applicant would limit its skilled care to assessing skin and UTIs but referring to other HHAs for resolution of problems. Please also clarify how the applicant proposes to reduce hospital knowledge deficits.

The attached documentation only shows the most common pump complications and the anticipated red flags with the intrathecal pump therapy. This was important to show based on the traditional result of pump complications. When an individual is being followed in the MD office, as the normal in Tennessee, the MD may not have the resources in staff, knowledge base, and or expertise in the therapy to quickly and efficiently identify potential problems. These potential problems will usually present as an emergency room visit and possibly a hospital stay. Utilizing IPM's service would allow the MD's an earlier approach to potential pump complications and in most cases eliminating those ER visits for the pump complications. It is very important to explain that the common emergency room staff and MD's do not have a programmer to read the pump, and in most cases do not fully understand the entire therapy. This lack of knowledge often times leads to extreme studies, imaging, and MD workups that are not indicated for the patient.

To clarify the described potential patient care enhancements. IPM will not only identify only changes in skin integrity and UTI's, but will identify to the MD and the patient any assessment that is found to be out of the "norm" This early identification of abnormal findings to patients and physicians is a pro-active approach to early identification and treatment of many secondary infections such as, changes in skin integrity, UTI's, pump site infections, abnormal heart rate, increases in blood pressure, SOB, and many others. The identified changes in skin integrity and UTI's were referenced because they are often very common in individuals with movement disorders, and or limited ambulation and or ROM due to chronic pain. IPM will identify and direct the patient to the MD and then coordinate with the MD the required care and coordinate with existing HHA's that provides the specific required service.

4. Section B, Project Description, Item V.4. (Home Health Agency) - Page 10-Is the RN not dispensing medications when taking the drugs to the patient? According to the Department of Health, dispensing medications outside of a physician's office constitutes a dispensing act which falls under pain clinic guidelines. Please explain how the plans for RNs to take drugs to the patient would be a permissible activity.

August 29, 2014 9:44 am

The IPM RN will not be dispensing medication to the individual patient. The contracted Infusion Pharmacy will be dispensing the medication to the patient and the RN will simply transport the medication to ensure temperature control and safety. The RN will be administering the medication based on the signed MD orders for the medication administration. The same scenario could be described as a home care RN bringing an intravenous antibiotic to the patient home for intravenous administration.

5. Section C, Need, Item 1 (State Health Plan) – Please summarize the key details of how the proposed service will "protect, promote and improve" the health of Tennesseans.

In summary the proposed intrathecal home infusion services will "protect, promote, and improve" the health of Tennesseans by offering specific, quality clinical care for implanted intrathecal pumps in the homecare setting. Focusing on a pro-active approach that identifies potential problems early for the best overall outcomes, both pump related and health related.

6. Section C, Need, Item 1 (Project Specific Criteria)

Items 1-4: the responses are noted. Please include utilization for 2013 in a revised Exhibit 1 (see HSDA worksheet attached to this correspondence). Also, it appears there are errors in the number of patients served & calculation of HHA capacity in Exhibit 2. Comparison of your response to the attachment sent with my August 13, 2014 e-mail revealed that the TDH worksheet-statewide calculation of HHA need should be used as the source/reference for this response. Please revise both exhibits.

Note: please recap how the indicators identified on pages 17/18 of your 7/28/14 supplemental response were determined. In revisiting that response, some confusion exists about IPM's ability to meet the 48 hour waiting time target for dose changes compared to 7-10 days for physicians. Also, how were the measures determined for the hospitalizations for pump complications (2/year per physician compared to the IPM rate of 0.2 per year?

Exhibit 1

Existing Licensed HHAS & Their Utilization serving the 95 County Declared Service Area

Agency Name (license #)*	County of Parent Office	Total Counties authorized in license (# counties in service area) **	2010 JAR Total patients served	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Clinch River Home Health #00000001 (01032)	Anderson	⁻ 7	596	473	468	461
Home Option by Harden Health Care (Girling) #00000148	Anderson	Unavailable	Unavailable	Unavailable	Unavailable	29
Professional Case Management of	Anderson	8	105	127	182	164

Melissa Hess August 28, 2014 Page 5

Tennessee #00000620 (01042)						
Heritage Home Health #00000004 (02024)	Bedford	7	286	282	280	241
Tennessee Quality Homecare – Northwest #0000008 (03025)	Benton	15	1129	1129	1128	1164
Blount Memorial Hospital Home Health Services #00000213 (05012)	Blount	19	1299	1357	1308	1224
Family Home Care, Cleveland #00000013 (06043)	Bradley	5	594	673	1023	598
Home Health Care of East Tennessee, Inc. #00000014 (06043)	Bradley	17	4976	4764	4755	3318
Sunbelt Homecare #0000016 (07032)	Campbell	10	246	285	260	261
Baptist Memorial Home Care #00000019 (09065)	Carroll	11	245	235	213	262
Amedisys Home Health Care #00000023 (10031)	Carter	7	1523	1241	1147	1171
Amedisys Home Health of Tennessee #00000025 (13022)	Claiborne	5	1272	1730	2074	1830
Suncrest Home Health #0000093	Claiborne	11	unavailable	unavailable	unavailable	852
Claiborne Home Health Care (13032)	Claiborne	Unavailable	504	436	unavailable	unavailab
Cumberland River Homecare #00000135 (14024)	Clay	10	313	361	236	392
Smoky Mountain Home Health and Hospice, Inc. #00000027 (15032)	Cocke	12	1699	1622	1535	1296
Doctor's Associates Home Health (16034)	Coffee	unavailable	787	unavailable	unavailable	unavailabl
Gentiva Health Services #00000030	Coffee	9	unavailable	unavailable	unavailable	424
Medical Home Health Care (16024)	Coffee	unavailable	1002	726	unavailable	unavailabl
Suncrest Home Health of Manchester, Inc #00000029	Coffee	15	unavailable	unavailable	unavailable	1588
C.M.C. Home C.A.R.E. #00000033 (18054)	Cumberland	1	545	536	409	407
Alere Women's and Children's Health LLC	Davidson	14	349	140	196	202

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#00000471 (19654)						
Amedisys Home Care #00000038? (19674)	Davidson	22	2881	1538	1598	2008
Amedisys Home Health #00000068? (19024)	Davidson	10	1443	756	388	5182
Amedisys of Nashville East #00000040 (19684)	Davidson	10	701	unavailable	unavailable	23
Angel Private Duty & Home Health (Friendship Private Duty) #00000622	Davidson	24	Unavailable	Unavailable	Unavailable	123
Careall (moved from Wilson county) #00000295	Davidson	22	Unavailable	Unavailable	Unavailable	1562
Continuous Care Services, LLC #00000048 (19664)	Davidson	6	788	905	671	407
Coram Specialty Infusion Services #00000624	Davidson	38	Unavailable	Unavailable	Unavailable	11
Elk Valley Health Services, Inc. #00000042 (19494)	Davidson	95	547	250	245	277
Friendship Home Healthcare, Inc. #00000323 (19614) N/A	Davidson	14	769	1040	1093	845
Friendship Private Duty, Inc. (19714)	Davidson	unavailable	9	10	unavailable	unavailable
Gentiva Health Services #00000049 (19084)	Davidson	12	1345	1239	1239	1003
Home Care Solutions #00000056 (19544)	Davidson	95	2140	unavailable	2080	1930
Home Health Care of Middle Tennessee, LLC #00000046 (19584)	Davidson	14	4017	4246	3914	2963
Innovative Senior Care Home Health	Davidson	22	unavailable	unavailable	Unavailable	677
Intrepid USA Healthcare Services #00000034 (19364)	Davidson	19	386	644	920	766
Maxim Healthcare Services, Inc. #00000615 (19704)	Davidson	9	154	138	141	106
Premiere Home Health, Inc. #00000035 (19374)	Davidson	1	113	118	81	87
Suncrest Home Health #00000070 (19324)	Davidson	12	4728	5428	6710	5490
US Bioservices (19504)	Davidson	unavailable	unavailable	unavailable	unavailable	Unavailable
Vanderbilt Community and Home Services	Davidson	20	1155	1180	1230	1879

#00000043 (19394)						
Vanderbilt Home Care Services #00000065 (19314)	Davidson	7	1049	1179	1268	1812
Willowbrook Home Health Care Agency, Inc. #00000259 (19694)	Davidson	36	3413	3088	2149	1565
Tennessee Quality Homecare – Southwest #00000221 (20045)	Decatur	15	1352	1352	1082	1080
Volunteer Homecare of West Tennessee, Inc. #00000063 (20055)	Decatur	17	1401	1598	1503	1534
SunCrest Home Health #00000060 (21024)	DeKalb	7	1282	1406	1501	1568
Regional HomeCare, Dyersburg #00000077 (23035)	Dyer	6	655	744	814	707
NHC Homecare #00000291 (24026)	Fayette	8	254	254	217	226
Where The Heart Is, Inc. #00000612 (24036)	Fayette	3	34	253	284	116
Quality Home Health #00000287 (25044)	Fentress	16	4059	4540	4012	3404
Quality Private Duty Care #00000080 (25034)	Fentress	5	461	599	703	879
Amedisys Home Care #0000082 (26054)	Franklin	16	1197	1015	1074	1150
Caresouth HHA Holdings of Winchester, LLC #00000083 (26024)	Franklin	34	1229	1395	1371	2030
NHC Homecare #00000085 (27025)	Gibson	12	546	479	625	569
Volunteer Home Care, Inc. #00000285 (27085)	Gibson	13	2443	2549	3027	3041
Advanced Home Care, Inc. #00000086 (30021)	Greene	7	323	385	526	762
Laughlin Home Health Agency #0000088 (30041)	Greene	5	608	553	547	655
Procare Home Health Services #00000087 (30051)	Greene	6	323	418	384	433
Amedysis Home Health Care #00000091 (32102)	Hamblen	13	3494	3613	3675	3896
Premier Support Services, Inc. #00000010 (32132)	Hamblen	30	839	972	900	1169

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University of TN		20				1327
Medical Center Home			3.			
Health Services	Hamblen	12	663	unavailable	1244	
#00000153 (32122)						
Alere Women's and		13				74
Children's Health, LLC	Hamilton		6	18	52	L.
#00000457 (33423)	T Adminition		ľ	10		
Amedysis Home Health		21				2878
#00000113 (33103)	Hamilton	21	2907	3358	3343	2070
Camellia Home Health		9				269
of Southeast TN #	Hamilton	1	Unavailabl	Unavailabl	Unavailabl	207
00000624	Taninito.		e	e	e	
Continucare		8				1466
Healthservices, IncI	Hamilton	0	1537	1638	1494	1100
#00000098 (33213)	Traininion		1557	1050	1424	
Continucare	<u> </u>	11				8
Healthservices, IncII	Hamilton	111	18	21	17	"
#00000108 (33383)	Hammon		16	21	17	
Gentiva Health Services		12				328
	Hamilton	12	459	487	268	326
#00000100 (33093)		7				1484
Guardian Home Care,	17	'	2122	2179	2116	1404
LLC #00000115	Hamilton		2122	2179	2116	
(33083)		1.7				Unavailabl
Home Care of	** ***	17	222	200	110	Unavanadi
Chattanooga #0000014	Hamilton		223	208	119	
(33133)		10	-			663
Home Care Solutions	Hamilton	10	401	unavailable	734	003
#00000338 (33363)		10				956
Life Care at Home of Tennessee #00000109	Hamilton	10	772	616	989	930
	Пашион		112	010	707	
(33303)		8				56
Maxim Hospital Home Health #00000613	Hamilton	l °	106	71	150	30
	Пашион		100	/1	150	
(33433)		11				2439
Memorial Hospital Home	Hamilton	111	3448	3469	3264	2439
Health #00000103	Hamilton		3446	3409	3204	
(33253)		11			-	354
NHC Homecare	Hamilton	111	207	199	203	334
#00000111 (33033)		4				463
Hancock County Home	Hamanak	4	342	299	323	403
Health Agency #00000117 (34011)	Hancock		342	299	323	
Deaconess Homecare		11				1330
	Hardin	111	1124	1213	1244	1330
#00000290 (36025)		1				241
HMC Home Health, LLC	Hardin	6	308	252	274	341
#00000137 (36035)		12				89
Hometown Home Health		3	122	172		09
Care, Inc. #00000320	Hawkins	1	177	173	unavailable	
(37021)		1 22				569
Regional Home Care,	TI do	22	692	570	616	309
Lexington #00000139	Henderson		683	579	616	
(39035)						

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Henry County Medical Center Home Health #00000122 (40075)	Henry	12	474	355	399	363
Hickman Community Home Care, Inc. (41034)	Hickman	8	154	9	134	214
Johnson County Home Health #00000130 (46031)	Johnson	2	408	251	396	446
Amedisys Home Health Care #00000150 (47202)	Knox	28	4958	3470	5420	5354
Camellia Home Health of East TN #00000144	Knox	22	Unavailabl e	Unavailabl e	Unavailabl e	1716
CareAll Home Care Services #00000131 (47232)	Knox	6	277	177	278	510
Covenant Homecare #00000133 (47402)	Knox	17	3940	2254	3946	3953
East Tennessee Children's Hospital Home Health Care #00000132 (47222)	Knox	16	1066	319	559	586
Gentiva Health Services #00000142 (47042)	Knox	16	812	636	870	779
Girling Health Care Services of Knoxville, Inc. #00000149 (47372)	Knox	Unavailable	1	0	1	Unavailable
Girling Health Care, Inc. (47182)	Knox	27	1130	760	1031	1467
Maxim Healthcare Services, Inc. #00000149 (47182)	Knox	18	210	83	150	159
NHC Homecare #00000143 (47012)	Knox	15	573	352	567	613
Priority Healthcare Services of Tennessee, Inc. (47062)	Knox	Unavailable	1513	unavailable	unavailable	Unavailable
St. Mary's Home Care Services (47092)	Knox	Unavailable	4206	unavailable	unavailable	Unavailable
Tennova Home Health # 00000151	Knox	15	Unavailable	unavailable	unavailable	3063
The Home Option by Harden Health Care	Knox	Unavailable	unavailable	unavailable	unavailable	Unavailable
University of TN Medical Center Home Care Services #00000156 (47132)	Knox	16	1877	1492	3264	3439
Deaconess Homecare #00000161 (52024)	Lincoln	25	604	381	704	842
Hospital Home Health and Hospice (52044)	Lincoln	unavailable	259	210	unavailable	Unavailable

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Lincoln Medical Home Health and Hospice # 00000160	Lincoln	7	unavailable	unavailable	unavailable	348
Home Care Solutions – Etowah #00000168	McMinn	4	Unavailable	Unavailable	Unavailable	283
NHC Homecare #00000166 (54043)	McMinn	8	234	117	183	239
Woods Home Health LLC (54083)	McMinn	unavailable	N/A	177	unavailable	Unavailable
Amedisys Home Health Care #00000177	Madison	19	2407	1618	2586	2741
Extendicare Home Health of West Tennessee #00000120 (57095)	Madison	21	1015	unavailable	993	1085
Intrepid USA Healthcare Services (57165)	Madison	15	210	168	86	422
Medical Center Home Health, LLC 00000174 (57055)	Madison	17	1329	810	1617	1706
Regional Home Care, Jackson #00000178 (57085)	Madison	20	969	755	1061	1164
Care All Homecare Services #00000194 (60074)	Maury	18	354	285	224	609
Maury Regional Home Services #00000180 (60044)	Maury	8	1022	1188	1220	1151
NHC Homecare #00000181 (60024)	Maury	21	2150	2212	2134	2408
Quality First Home Care #00000090 (60084)	Maury	5	877	906	855	923
Intrepid USA Healthcare Services #00000190 (62052)	Monroe	15	240	238	273	358
Sweetwater Hospital Home Health #00000189 (62062)	Monroe	5	470	462	569	613
Gateway Home Health, Clarksville #00000186 (63034)	Montgomery	7	873	1050	1067	949
Suncrest Home Health of Nashville #00000293	Montgomery	11	Unavailable	Unavailable	Unavailable	587
Extendicare Home Health of Western Tennessee #00000188 (66035)	Obion	5	499	398	347	302
Amedisys #00000191 (67024)	Overton	11	1355	1325	1277	1453
Highland Rim Home	Putnam	14	597	555	495	574

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Health Agency #00000197 (71014)						
Intrepid USA Healthcare Services #00000198 (71084)	Putnam	8	275	244	341	327
Lifeline Home Health Care #00000203 (74064)	Robertson	5	325	289	336	428
NHC Homecare #00000205 (74054)	Robertson	7	830	869	909	1332
Amedisys #00000207 (75054)	Rutherford	7	613	543	554	661
Amedisys Home Health Care #00000005 (75064)	Rutherford	19	1315	1476	1431	1582
NHC Homecare #00000208 (75024)	Rutherford	24	2794	3007	3269	3776
Deaconess Homecare #00000211 (76032)	Scott	5	402	406	352	394394
Accredo Health Group, Inc. #00000347 (79456)357	Shelby	6	7	9	14	2020
Alere Women's and Children's Heal2411th LLC #00000459 (79466)576	Shelby	7	4	357	401	417
Amedisys Home Care #00000239 (79146)	Shelby	3	789	892	938	1060
Amedisys Home Health #00000215 (79386)	Shelby	3	2344	2411	1806	1934
Amedisys Home Health Agency, Inc. #00000238 (79256)	Shelby	4	567	576	683	936
Americare Home Health Agency, Inc. #00000216	Shelby	2	Unavailable	Unavailable	Unavailable	1811
Baptist Trinity Home Care #00000241 (79276)	Shelby	4	3314	3248	3367	3862
Baptist Trinity Home Care – Private Pay Division #00000242 (79446)	Shelby	5	1	1	I	1
Best Nurses, Inc. #00000621 (79546)	Shelby	3	41	311	366	364
Elder Care, Inc. (79136)	Shelby	unavailable	421	780	unavailable	Unavailable
Extended Health Care, Inc.#00000120	Shelby	6	unavailable	unavailable	unavailable	79
Family Home Health Agency #00000229 (79206)	Shelby	2	1070	375	863	379

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		La	1			052
Functional Independence Home Care, Inc. #00000610 (79496)	Shelby	3	903	unavailable	804	953
Home Health Care of West Tennessee, Inc.	Shelby	4	1617	unavailable	1118	1010
#00000227 (79486) Homechoice Health Services #00000240 (79376)	Shelby	6	2963	unavailable	unavailable	861
Interim Healthcare of Memphis, Inc. #00000228 (79056)	Shelby	3	727	720	889	769
Intrepid USA Healthcare Services #00000214 (79226)	Shelby	3	537	662	615	605
Maxim Healthcare Services, Inc. #00000618 (79536)	Shelby	6	82	103	197	155
Meritan, Inc. (Senior Services Home Health) #00000237	Shelby	4	Unavailable	Unavailable	Unavailable	609
Methodist Alliance Home Care #00000233 (79316)	Shelby	7	3352	3226	3180	3179
No Place Like Home, Inc. #00000611 (79506)	Shelby	3	48	38	55	58
Senior Services Home Health (79106)	Shelby	unavailable	670	642	127	Unavailable
Still Waters Home Health Agency, LLC #00000616 (79526)	Shelby	1	83	105	unavailable	101
Willowbrook Visiting Nurse Association, Inc. #00000244 (79236)	Shelby	6	451	479	533	479
Sumner Homecare and Hospice, LLC (Highpoint Homecare) #00000245 (80064)	Smith	8	316	212	unavailable	377
Advanced Home Care, Inc. #00000249 (82051)	Sullivan	5	2665	2825	2583	2245
Gentiva Health Services #00000251 (82061)	Sullivan	9	1244	1286	979	936
Highpoint Homecare #00000258	Sumner	7	unavailable	unavailable	unavailable	855
Sumner Homecare and Hospice, LLC #00000258 (83114)	Sumner	7	1102	978	unavailable	Unavailable
Baptist Home Care and Hospice – Covington #00000260 (84046)	Tipton	8	330	326	361	353
CareAll Homecare Services #00000288	Tipton	19	1424	1491	unavailable	1556

(84076)						
Unicoi County Home Health #00000355 (86051)	Unicoi	1	205	246	209	206
CareAll Home Care Services #00000265 (89074)	Warren	10	515	520	337	637
Friendship Home Health, Inc. #00000619 (89084)	Warren	10	1083	1025	1345	1724
Intrepid USA Healthcare Services #00000263 (89064)	Warren	16	506	650	159	822
Amedisys Home Health #00000273 (90121)	Washington	7	2905	2496	2384	1821
Medical Center Homecare Services #00000271 (90091)	Washington	6	2667	2801	3118	3503
Medical Center Homecare, Kingsport #00000269 (90081)	Washington	7	1298	1126	1628	1960
NHC Homecare #00000267 (90131)	Washington	7	279	241	264	259
CareAll Homecare Services #00000276 (92025)	Weakley	13	1902	1903	unavailable	2036
Guardian Home Care of Nashville, LLC #00000607 (94074)	Williamson	14	1982	1265	1365	1370
Health at Home #00000617	Williamson	1	unavailable	unavailable	unavailable	58
Home Health Care Services, LLC (Health at Home) #00000617 (94094)	Williamson	1	62	63	Unavailable	Unavailable
Vanderbilt HC Affiliated w/ Walgreens #00000604	Williamson	33	Unavailable	Unavailable	Unavailable	67
American National Home Health	Wilson	unavailable	unavailable	unavailable	unavailable	311
CareAll (95064)	Wilson	Unavailable	1680	1473	Unavailable	Unavailable
Deaconess Homecare #00000282 (95034)	Wilson	21	1076	1237	1210	1222
Donelson Home Health (95074)	Wilson	unavailable	1931	1705	unavailable	Unavailable
Gentiva Health Services	Wilson	unavailable	unavailable	unavailable	unavailable	1380
Quality Care Home Health Agency (95084)	Wilson	unavailable	128	217	unavailable	unavailable
Magnolia Regional Health Center Home Health #00000296 (96010)	Out-of-State	2	1009	1000	915	856

Professional Home Health Care Agency, Inc. #00000298 (96030)	Out-of-State	7	2920	3021	2985 ^T	2641
Regional Home Care Parkway #00000297 (96020)	Out-of-State	2	23	31	14	28

				Exhibit 2					Marie Control
Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Tennessee	1,619	1,457	175,924	6,528,014	0.0269	6,833,509	184,157	102,503	(81,654)
Anderson	22	19	2,893	76,182	0.0380	77,851	2,956	1,168	(1,789)
Bedford	20	19	1,120	46,700	0.0240	50,566	1,213	758	(454)
Benton	11	10	667	16,315	0.0409	16,104	658	242	(417)
Bledsoe	10	8	462	12,698	0.0364	12,599	458	189	(269)
Blount	18	18	2,507	126,809	0.0198	135,171	2,672	2,028	(645)
Bradley	16	14	2,021	102,235	0.0198	107,481	2,125	1,612	(512)
Campbell	21	18	1,715	41,163	0.0417	42,566	1,773	638	(1,135)
Cannon	19	16	423	14,013	0.0302	14,540	439	218	(221)
Carroll	13	13	1,246	28,213	0.0442	27,831	1,229	417	(812)
Carter	12	11	2,072	57,228	0.0362	57,680	2,088	865	(1,223)
Cheatham	24	25	772	39,603	0.0195	40,765	795	611	(183)
Chester	14	13	563	17,355	0.0324	17,999	584	270	(314)
Claiborne	19	15	2,002	32,457	0.0617	33,280	2,053	499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673	249	115	(133)
Cocke	16	14	1,467	36,330	0.0404	38,615	1,559	579	(980)
Coffee	20	16	1,874	53,784	0.0348	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0369	14,683	541	220	(321)
Cumberlan d	15	13	1,601	57,370	0.0279	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0230	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0542	12,080	655	181	(473)
DeKalb	21	16	469	18,918	0.0248	19,125	474	287	(187)
Dickson	25	24	1,617	50,596	0.0320	51,964	1,661	779	. (881)
Dyer	11	10	1,671	38,205	0.0437	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0178	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0346	42,122	1,459	632	(828)
Gibson	15	14	1,924	50,748	0.0379	52,163	1,978	782	(1,195)
Giles	12	_ 11	1,001	29,325	0.0341	29,285	1,000	439	(560)
Grainger	22	20	886	22,994	0.0385	23,675	912	355	(557)
Greene	20	17	2,454	69,888	0.0351	71,594	2,514	1,074	(1,440)
Grundy	18	16	529	13,396	0.0395	13,293	525	199	(326)
Hamblen	19	17	2,835	63,763	0.0445	65,570	2,915	984	(1,932)
Hamilton	16	16	8,038	345,447	0.0233	353,577	8,227	5,304	(2,924)
Hancock	14	11	682	6,652	0.1025	6,640	681	100	(581)

SUPPLEMENTAL #3

Hardeman	17	15	917	26,492	0.0346	26,067	902	391	(511)
Hardin	16	14	1,157	25,968	0.0446	26,244	1,169	394	(776)
Hawkins	21	18	2,148	57,273	0.0375	58,164	2,181	872	(1,309)
Haywood	15	13	612	18,199	0.0336	18,009	606	270	(335)
Henderson	14	13	1,015	28,080	0.0361	28,631	1,035	429	(605)
Henry	10	10	1,283	32,595	0.0394	32,956	1,297	494	(803)
Hickman	18	17	725	24,393	0.0297	24,698	734	370	(364)
Houston	12	11	281	8,358	0.0336	8,447	284	127	(157)
Humphreys	16	14	803	18,488	0.0434	18,561	806	278	(528)
Jackson	12	11	402	11,355	0.0354	11,495	407	172	(235)
Jefferson	20	19	1,749	53,006	0.0330	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
Lake	6	5	325	9,795	0.0332	9,468	314	142	(172)
Lauderdale	14	11	857	27,465	0.0332	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0312	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0334	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0332	35,697	1,116	535	(580)
Loudon	23	21	1,572		0.0313				
McMinn	17	17		50,356		53,192	1,661	798	(863)
			1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315	101,001	3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256	28,992	743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomer	40	20	0.000	404.007	0.0450	000 504	0.400	0.000	(454)
Y Manage	19	20	2,903	184,087	0.0158	200,561	3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216	22,004	476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	(141)
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256	16,588	425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)
Stewart	10	10	339	13,436	0.0252	13,941	352	209	(143)

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Sullivan	14	13	5,259	158,451	0.0332	161,136	5,348	2,417	(2,931)
Sumner	26	27	4,160	169,409	0.0246	183,406	4,504	2,751	(1,753)
Tipton	26	22	1,298	63,001	0.0206	67,545	1,392	1,013	(378)
Trousdale	16	14	431	8,046	0.0536	8,582	460	129	(331)
Unicoi	13	11	659	18,334	0.0359	18,511	665	278	(388)
Union	21	18	371	19,231	0.0193	19,605	378	294	(84)
Van Buren	12	11	240	5,456	0.0440	5,474	241	82	(159)
Warren	20	15	2,266	40,299	0.0562	41,155	2,314	617	(1,697)
Washingto n	16	14	4,181	128,537	0.0325	138,370	4,501	2,076	(2,425)
Wayne	11	9	640	16,887	0.0379	16,724	634	251	(383)
Weakley	13	11	1,180	38,255	0.0308	39,491	1,218	592	(626)
White	14	9	962	26,612	0.0361	27,974	1,011	420	(592)
Williamson	32	32	2,815	198,045	0.0142	223,333	3,174	3,350	176
Wilson	28	31	3,727	121,626	0.0306	133,357	4,086	2,000	(2,086)

<u>Item 5A</u> — As noted, it is important to justifying the need for the service by providing letters of support and related correspondence from physicians who will issue orders for patient services in the home regardless of whether or not the referrals come from the pump vendor representatives. This criterion cannot be met without letters from physicians, at least documenting a need for the service in lieu of a letter of support for IPM (the company). Given the provision of the service by Camellia Home Health Agency in 28 counties of East & Southeast Tennessee, including Knox and Hamilton Counties, it seems that physicians from these areas utilizing the IP home infusion service would be able to speak to the need for the service in their community(s). Please provide the documentation requested in the application and supplemental questionnaires.

IPM has not been able to obtain letters of support from referring physicians without a valid home health license.

<u>Item 5B</u>—It appears the response indicates 60 referrals by physicians following implantation and 60 referrals from physicians that mange patients with existing pumps for a total of 120 cases in Year 1. Of the 120 total patients, how many are patients with chronic pain, CP and MS clinical conditions (targeted populations identified on page 28 of the supplemental response)?

The breakdown of patients by diagnoses can only be guesstimated, as IPM does not have access to the Medtronic database of pump implants based on medical diagnoses. IPM does though feel that the estimated breakdown from the total number of 120 to be as indicated.

Chronic Pain 108 Multiple Sclerosis 2 Cerebral Palsy 11

<u>Item 6A - In light of the projected operating expenses and patients in the projected Data Chart, the average cost per patient seems to be approximately \$1,263/ patient in Year 1 (\$151,500 divided by 120 projected patients). However, when looking at a cost per visit measure, the applicant's cost of \$100 per visit appears reasonable. Please confirm the projected <u>average cost per patient</u> in Year 1 of the project.</u>

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IPM would like to confirm that we have projected an average cost of \$100 per each patient visit. IPM has also projected to see each patient once monthly. Therefore, IPM's projected average cost per patient is approximately \$1200 per year.

7. Section C, Need, Item 6 -

Using the target population data on pages 28-30 of your 8/18/14 supplemental response, it appears that individuals with chronic pain account for approximately 90% of the total target patient population, followed by Cerebral Palsy (9%) and Multiple Sclerosis (1%) patients. Is this a predictor of the applicant's 120 patient caseload in Year 1 increasing to 240 patients in Year 2? If so, what are the projections by each category?

Yes, the predictor of IPM's 120 patient caseload that increases to 240 in year two is based on the assumption of the percentages of the above question. The same guesstimates would be used, chronic pain 90%, MS 1% and Cerebral Palsy 9%.

Since the applicant is targeting only private pay or commercial insurance based on coverage availability, what assurances can the applicant provide that the IP service will be a covered service by commercial or managed care plans and that managed care plan networks have a need for the proposed service? Please identify major commercial plans that include IP home infusion as a covered service in their networks.

Since IPM is not a Medicare certified agency, Medicare plans will not reimburse IPM for services provided to Medicare recipients. Therefore IPM is targeting the patient population covered by private pay or commercial insurances. IPM will receive assurance that the service will be covered prior to providing the service by conducting a verification of benefits over the phone with the commercial insurance plan. Unlike Medicare, almost ALL commercial insurance plan networks include a benefit for inhome nursing services. IPM does not believe it is the managed care plan that necessarily has a need for IPM's proposed service. IPM is proposing a service that will benefit patients with intrathecal pumps and the physicians managing these patients.

8. Section C, Orderly Development, Item 2

What effect will limiting admissions to patients with private or commercial insurance have on existing providers, especially hospitals and physicians that are closer to the patient to respond to patient emergencies?

While the service is currently being provided in the East Tennessee by an existing HHA, the proposal has a unique opportunity to be the first service offered by a HHA in the Middle and West Grand Divisions of Tennessee, if approved. What consideration was given to providing the service in counties of the Middle and West Tennessee Grand Divisions and/or counties where the target populations are highest (MS,CP and chronic pain) in order to prevent duplication with the existing HHA that serves 28 counties located in the East Grand Division of the state?

Please summarize the benefits of the proposal and address how these might outweigh the potential risks in terms of patient safety.

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The affect of limiting admissions that are not required to patients with commercial and or private payers will not adversely affect the area hospitals and emergency rooms. The fact remains that the majority of hospitals and emergency rooms are not equipped with the necessary programmers and staff trained to handle the intrathecal pumps. This introduction of services will not eliminate all ER and hospital admissions, only the un-necessary ones related to the pump trouble shooting and or potential pump problems. The individual population will still utilize the local ERs and hospitals for other non- pump related emergencies in addition to pump reimplantations. The Medtronic Intrathecal Pump must be surgically replaced every five to seven years depending on rate of flow.

Although the service is currently being provided in the East Grand Division of Tennessee by an existing HHA, IPM still feels that the introduction of another HHA to provide the therapy will only benefit the individual pts. The existing HHA provides many other services other than intrathecal home infusion management, so the introduction of IPM services to the East Grand Division of Tennessee would not be a direct competitor for the existing HHA's pt population. IPM is also hoping to refer individuals requiring services not provided by IPM to the existing HHA in the East Grand Division of Tennessee.

In summary the proposal is to introduce specialty services of intrathecal home infusion management to the entire state of Tennessee. IPM does recognize the safety implications and potential risks that come with this therapy. The risks are inherent and cannot be completely removed. IPM will create a specialty RN workforce that has a sole focus on the proposed therapy with several safety checks, quality control, and safeguards that promote optimal safety and positive patient outcomes.

9. Section C, Orderly Development, Item 7.c. Item 7c: For purposes of clarification and consistency, the response to this item on page 30 of the revised application noted operations in New Jersey and Florida (recent JCAHO accreditation). Please describe how these entities are licensed, the types of services being provided and the number of patient served for the most recent 12 month period.

IPM currently has locations in New Jersey as well as Florida. We hold accreditation by the Joint Commission for our Florida location (see Attachment 9.Section C.Orderly Development.Item 7C) and are currently anticipating the receipt of our home health licensure within this state. We do not require this licensure within the State of New Jersey as our provision of just a single service exempts us from this requirement. We are not currently servicing patients within the state of New Jersey.

10. Revised Application Questions and Additional Questions

Based on HSDA staff review of the revised application and input from HSDA partners, some additional questions for clarification are provided in **Exhibit 1** and **Exhibit 2** attached to this letter. The intent of the questions is to provide the applicant with an opportunity to present the proposal in a summary format. While HSDA staff apologizes if the questions are similar to questions in prior Supplemental Questionnaires, please answer all questions in the order provided. If the applicant feels that the question has been addressed previously, please include the date of the supplemental response, item # and page that applies in your response. Thank you for

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your interest and consideration in helping HSDA complete initial review of your application.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60th) day after written notification is September 23, 2014. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the <u>next review cycle</u>, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. \ni 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please contact this office.

Sincerely,

Jeff Grimm HSD Examiner Enclosure

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Exhibit 1 - Additional Clarification - Revised Application

- I. Section B, Project Description, Item 1
- 1. Page 10, 1st paragraph—the applicant states that its services will be provided to patients in their home and in third party facilities. Please define the term third party facilities (types that might apply) and give examples of the nature and scope of services that IPM plans to provide as a licensed home health agency limited to IP home infusion management.

On page 10, first paragraph, it is stated that IPM will provide services to patients in their homes and third party facilities. Third party facilities refer to in-patient hospital stays, long term care facilities, and or possibly rehabilitation facilities. In the event that IPM must enter a third party facility to refill and or titrate a patient. IPM will gain authorization from that individual facility. Based on the specific therapy, most hospitals and or other type of facilities do not have the resources to manage the intrathecal pump.

2. Page 11, 1st paragraph- the applicant states that the RN staff will be rigorously trained in all aspects of pump management. Please define rigorously trained. In your response, please include a description of the type of training a nurse must complete to provide this service, including training on management of implanted pumps taught in nursing schools, if any.

The Board of Nursing Rules require that the RN be licensed and be competent (have the education and training) to perform any anticipated services; please document how the RN is trained to be competent and how the RN will retain those competencies.

The training for an IPM RN consists of two days of theory, mechanics, and medications utilized for the therapy. The second phase of training focuses on the programmer (device used to program the pump) and the refill procedure done in a classroom setting. The next phase is clinical practice with the refill and programming through required programming tests and successful demonstration of pump refill techniques through utilizing a "dummy" patient. At this point in the training the IPM RN would be able to observe home visits. The IPM RN in training will work with an IPM RN licensed in the state of Tennessee for practical and clinical experience and proficiency. The training RN must demonstrate accurate knowledge of the pump system, all components and steps for programming and refill at least three times supervised for every level of pump. IPM grades each pump from 1 to 3 based on difficulty level of palpation, identification of borders, and refill procedure. Please see

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Attachment 2.Section B.Project Description.Item 1.Item J for documentation of training. To the best of IPM's knowledge, nursing schools do not train on intrathecal pump management. The modality is referenced, but not expounded upon. Each nurse will be subjected to yearly clinical reviews, and un-scheduled clinical spot-checks to evaluate policy adherence to safety and pump training. Each RN will also be required to participate in quarterly continuing education created by IPM and Medtronic for enhancing further knowledge in regards to the intrathecal pump.

3. Page 11, 2nd paragraph-financial viability is identified as one of the admission criteria. A search of the medical literature on intrathecal pumps revealed that they are used to relieve cancer pain with medication costs covered under Medicare and other insurance (apmsurgery.com). While not taking TennCare may certainly enhance IPMs financial viability, what effect will IPM's plans to limit the service to private or commercial insurance patients have on hospitals, ambulatory surgery center/pain management clinics and physician offices who currently provide these services? In addition, what commercial plans have opportunities for participation in their networks by IPM (please provide documentation of this need)?

Since IPM is not a Medicare certified agency, Medicare plans including TennCare will not reimburse IPM for services provided to Medicare recipients. Medicare only covers services done by Medicare Certified Agencies. Therefore, patients covered under Medicare or TennCare will not be eligible for home infusion nursing services through IPM. This factor will only affect the physician because these individuals would need to continue to receive their intrathecal infusion services by their physician in the office. The other settings mentioned in this question were hospitals and ambulatory surgery centers which will remain unaffected. In regards to becoming participating providers for the commercial insurance plans, IPM has intentions to submit applications to these plans once IPM is established. However, participating provider status is not necessary for insurance coverage of services with most plans.

4. Page 11, 2nd - 4th paragraphs- care model and responsibilities are addressed and identified. Please provide a detailed summary of implanted pump from the time the pump is inserted by the physician to the ongoing care needed. In your response, please address each of the following:

Will there be MD supervision during the administration of the service and in follow-up care situations?

Who will determine refill dosage and regimen changes?

Who will evaluate and manage complications arising from the pump treatment? What assurances will be provided to insure the compounding pharmacy chosen is practicing FDA recommended guidelines?

A detailed summary of the implanted pump for the time the pump is inserted by the

physician to the ongoing care required follows.

The implanting physician implants the intrathecal pump after a successful trial has been done to establish efficacy with the therapy. The implanting physician can chose to manage the patient in regards to patient dosaging, refills, therapy changes, or refer them to a managing physician. IPM works directly with ordering MD's and implements MD orders in the homecare setting for the home management of the intrathecal pump. When the RN is in the home with the patient, the MD will not be

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physically there with the RN. The RN will be trained to alert the MD of any abnormal findings during the patient encounter. The MD is therefore allowed an insight on the patients living condition, dynamics and also a full nursing assessment from a RN focused on intrathecal pump management. It is important to emphasize that the ordering MD will still need to see the patient in the MD office. The frequency of required visits will be controlled and set by the ordering MD. When the patient does go to the office, that patient will be filled, assessed and titrated by IPM RN's. This will allow the MD the ability to focus on the patient and not on a clinical procedure, i.e.: pump refill or titration. The ordering MD will have access to clinical computerized records via a secure website 24 hours of every day, the clinical records including telemetry, assessments and nursing notes will be available. The ordering MD determines and orders all changes done in regards to the intrathecal pump, Dosage, Concentration, Refills, Medications, Visit frequency is all implemented by IPM RN's directly from a MD order. No MD orders will be carried out without a signature for implementation. In the event that IPM recognizes or suspects a potential pump complication the ordering MD will be made aware and the MD will manage and evaluate any potential concerns. The ordering MD has full control of the patients' intrathecal management program. IPM will serve only as an "extension" of services to the MD. The contracted compounding pharmacy will be researched and must provide documentation of successful pharmacy surveys, JCAHO accreditation and also compliance with all 797 Pharmacy Standards.

II. Section B, Project Description, Item II.C.8. (page 12)

1. Please provide additional details explaining how providing this service in the home can reduce the time to implement the care from 2 weeks by a physician practice to 48 hours by IPM.

IPM can reduce the amount of time that an intrathecal pump patient must have to wait to see a MD for an ordered titration greatly. The typical MD office will take up to a week for an appointment with the MD, IPM can respond within 48 hours or less with a titration order. The individual whom has to travel to the MD office for dose changes also faces a possible economic hardship due to price of gasoline. or possibly a logistic problem, requiring a caregiver to take the individual. The response time for titrations is greatly reduced if a patient can take advantage of the home management program.

2. For continuity of care, if an existing patient needs an increase in the amount of medication, such as an opioid-based drug, would the physician call the order into IPM or a local pharmacy without first seeing the patient to complete an assessment, take and report laboratory values to assess dosage levels, etc.? Who is responsible if the patient is admitted to a hospital? In an emergent situation, such as an overdose, what will be done to manage the situation? What happens if the treating physician does not have admitting privileges at the nearest hospital?

If a patient has had any change in pain and or spasticity level the IPM nurse will evaluate the individual and alert the MD of the findings. If after reviewing the nurse assessment, or a MD assessment the MD would like to make a dose change then the MD will send a signed order to IPM for implementation. A simple dose change does

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not require pharmacy involvement because the medication is in the pump, the rate of flow delivered must be changed to implement the MD order. The intrathecal pump has a reservoir that acts as a "holding tank" for medication. For a dose increase or decrease no new medication is required, just programming. Due to the fact that the medication is delivered directly into the cerebrospinal fluid, the medication does not cross the blood brain barrier, therefore not entering the systemic system, so no labs or any other testing is required for this therapy for maintenance. In the event that the individual is admitted to the hospital the ordering is ultimately responsible, but IPM will work with the MD to assist if possible. In the event of an overdose, which could occur as a result of a programming error or a subcutaneous pocket fill, the pt will go to the ER for immediate evaluation. IPM has polices for their RN's in the event of a suspected pocket fill to call 911, monitor vital signs, stay with the patient until EMT arrives and call the ER to alert them of the situation. In the event of a pocket fill, IPM assumes full liability. The MD is responsible for making sure their orders are correct, but does not maintain responsibility for the pump refill. IPM assumes all of that responsibility. To manage the situation in the event of an over dose or pocket fill, the pt will be monitored for airway, have the pump turned to "minimal rate" and possibly a lumbar puncture to remove fluid to decrease the concentration of medication in the cerebrospinal fluid.

III. Section B, Project Description, Item V.3.

Please provide a summary of the details regarding the proposed draft contract with the compounding pharmacy in Louisiana. What services will be provided, will drugs be shipped to the Knoxville office for all of IPMs patients or will the patients have a choice in where they obtain the medications? Are these contracted services accounted for in Line D.8 of the Projected Data Chart (other expenses)?

Services provided by this pharmacy, as indicated within our previously provided contract template (see Attachment – Exhibit 1.Additional Clarification III.Section B.Project Description.Item V3), include the compounding and dispensing of medication as instructed by IPM staff and according to physician orders as well as consultation regarding medication.

Medications will be shipped by the pharmacy directly to our RNs for delivery to IPM patients – there will be no exceptions to this policy. Patients will not choose where they obtain medication from. Pharmacy services are not accounted for within our projected data chart since the pharmacy will be billing for all medication directly.

IV. Section C, Need, Item 1 (Project Specific Criteria - Home Health Services)

1. Page 20, 1.a.1-There are currently 157 licensed home health agencies in Tennessee. Many have branch offices located in other counties within their service areas with nursing staff stationed in those counties ready to deliver services in much less than 48 hours. Please explain why establishing another limited service home health agency that would deal only with pump related services is a better option than an existing agency training its existing staff to provide the full range of services the patient might require.

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The establishment of a statewide intrathecal home management program would be beneficial because although there are over 100 licensed HHA's in the state only two of those HHA's off this specific therapy. This therapy is unlike any other intravenous infusion and requires a much higher skill set and sole focus. IPM is confident that the existing agencies are ample to offer all other home care services required, but not intrathecal homecare management. This opinion is cemented by the fact that out of 157 licensed HHA's in the state of Tennessee, only two provide the therapy and very minimally at that. The therapy is so specialized; success is contingent on a sole focus and highly trained staff.

2. Page 22, 1.a.6- If no comparison charges are available from other home health agencies, please provide the charge data for this type service in a physician's office.

The documented data from Medtronic for an intrathecal pump refill in the MD office setting is approximately \$121/visit (please see Attachment – Exhibit 1.Additional Clarification IV.Section C.Need.Item 1 for Medtronic reimbursement rates).

3. Please provide a definition of an MRI check and how this relates to the proposed IP home infusion service.

The definition of a MRI check is as follows. Medtronic requires the intrathecal pump to be interrogated at least 15 minutes or up to 2 hours post MRI exposure. The rationale for this policy is that the EMI (electromagnetic interference) can cause the pump motor to stall; Medtronic has developed the pump motor to stall to protect the system under high exposure of EMI. The pump must be interrogated (read with a programmer) post MRI to ensure that the motor stall has "recovered" This is essential because abrupt cessation of intrathecal therapy will cause severe withdrawals for the patient.

V. Section C, Need, Item 4.a (Service Area)

1. Page 23- last paragraph- Staff was under the impression that physicians may adjust medications based upon lab values based on lab samples taken by IPM. Please clarify by describing the process that will apply.

The impression that physicians may adjust medications based upon lab values is not correct in regards to this therapy. Lab values are not used for therapeutic levels as in other systemic medications. The medication does not cross the blood brain barrier; therefore lab results would not be of a benefit. The ordering MD will assess the patient based on pain and or spasticity level, functional changes and overall general response to therapy.

2. Page 24, 4.b.-Since age and income directly relate to a person's ability to qualify for Medicare and Medicaid, how can the applicant indicate that it will "aggressively attempt to provide our services to any patient in need of pump

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management" in light of the high number of Tennesseans enrolled in Medicare and TennCare (approximately 2.3 million Tennesseans participate in these programs)?

IPM has indicated that we will "aggressively attempt to provide our services to any patient in need of pump management" based on our attempt to look at every individual on a case-by-case basis. For many individuals, traditional Medicare does not offer a home infusion benefit, but many of the Medicare Advantage Programs (MAP) do include a homecare benefit. IPM will provide information to make the patient aware of the possible option for homecare.

VI Section C, Need, Item 6

Page 23 - What percentage of the 300 Medtronics pumps are utilized by Medicare and TennCare enrollees?

Of the 300 Medtronic Pumps in Tennessee IPM is unable to provide the individuals whom are TennCare and Medicare enrollees. This information is not available to IPM from Medtronic.

VII Section C, Orderly Development, Item 7

Page 30, - what license type does IPM have to provide services in New Jersey and Florida? In your response, please document with a copy of the Joint Commission Certificate and appropriate state license.

Please see attached TJC award letter indicating our Florida accreditation (Attachment – Exhibit 1.Additional Clarification IIV.Section C Orderly Development.Item 7). We are currently in the process of obtaining applicable home health licensure within the state of Florida.

Since New Jersey does not require a home health provider to obtain licensure if only administering a single skilled nursing service, IPM does not hold home health licensure within this state. Please refer to Attachment — Exhibit 1.Additional Clarification VII.Section C Orderly Development.Item7 for applicable NJ regulations, which define a home health agency as a facility that provides "at a minimum nursing, homemaker-home health aide, and physical therapy services and are eligible for Medicare-certification."

Exhibit 2 - Additional Questions Summarizing Administration of Proposed Service

I. Administration of Home Service – General Licensure Requirements

1. Is any certification required or available for performing IP services? The Board of Nursing Rules require that the RN be licensed and be competent (have the education and training) to perform any anticipated services; the applicant therefore must document how the RN is trained to be competent and how the RN will retain those competencies. High risk of overdose due to high conversion

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ratio requires adequate experience with IPs and with interventional pain medication.

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There is no national accreditation for RN's to perform for intrathecal homecare management. The specific training that IPM conducts with the homecare RN is specific, detailed, and accepted by Medtronic (please see Attachment 2.Section B Project Description.Item 1.Item J). The state Tennessee Board of Nursing rules "that the RN be licensed and competent to perform the skill" will be proven through study, clinical presentation, and rigorous training and ongoing continuing education modules. IPM understands the concern regarding high concentrations of pain medications and the potential for error with the proposed therapy. This reason, among others is why IPM feels strongly that a sole therapy approach is the safest and only approach for patient safety and success of the intrathecal therapy. A professional RN must be able to learn and master a plethora of skills to perform their individual job responsibilities. IPM gives the RN the luxury of a single focus of intrathecal homecare management, therefore increasing success and decreasing and or eliminating the risk for error with intrathecal homecare management.

2. The continuity of care should lie with the implanting physician or the primary care provider following the patient's release from surgical care. The response provided by the applicant in Item 4 of Supplemental 2, clarified that there will be a "therapeutic arrangement or helping alliance" between IPM and the patient's managing physician where IPM serves as an extension of the physician. What are the key terms of the proposed contract between IPM and the patient's managing physician that address continuity of care and related responsibilities of the parties, including responsibilities for the patient's follow-up care such as the development & communication of patient care plans between IPM and the managing physician, frequency of RN visits with each patient, etc.?

The continuity of care required between IPM and the managing physician is not in the contract between the physician and IPM. The coordination of care contract serves only to indemnify the physician of any liability with programming, and refilling the pump. The physician is solely responsible for writing and signing the correct medication orders. This does not relieve the physician of the inherent need for managing this individual pt. The alliance between IPM and the physician serves essentially as a bridge and assistance to the physician to assist in the implementation of the intrathecal implanted pump. IPM does not presume to take any more responsibility away from the ordering MD. IPM does however; fully plan on assisting the patient and physician in coordinating and indentifying any further needs that the individual patient might have unrelated to the prescribed pump therapy. IPM wishes only to become an "extension" of the MD office in regards to the intrathecal implanted pump.

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II. Administration of Home Service - Risks

There are risks of coordination of care, infection, diversion, overdose, and equipment malfunction/troubleshooting. Please address these matters in the questions that follow below.

1. It appears that the physician, pharmacist and RN will not be together to perform cross checks of the pump for dosage and adjustment of medications. As such, physician review of patient condition is dependent upon report by RN, rather than face-to-face assessment by physician. Please describe how coordination between the parties will occur. Please also describe the process for "troubleshooting" the IP.

It is correct in stating that the physician and RN will not be face to face to perform crosschecks on the dosages, syringes and titrations of medications. The process will be as follows:

- a. The physician will write an order for medication and or dosage change for the individual patient
- b. If a new syringe is required, the order will be sent to the compounding pharmacy for creation
- c. The compounding pharmacy will send the medication to the primary RN.
- d. The primary RN, upon receiving the medication, will do a medication check with the on-call administrator
- e. The medication check will check: pt name, DOB, color, clarity, volume, medication, concentration, daily dose, and sterile, tamper free cap.
- f. All required indicators will be documented and double checked with the signed MD order on file
- g. After accuracy is confirmed the RN will travel to the pt home for implementation
- h. The next safety check at the pt home is to confirm the anticipated pump settings with the syringe in hand. At this point if there are any discrepancies, the RN will not proceed but call the on —call administrator for guidance.
- i. The home RN will perform the ordered changes, double-checking anticipated volume compared to actual, new pump settings, and a full review with the pt of the new telemetry to confirm, line-by-line accuracy. (The telemetry shows settings at first reading, and any updated settings.)
- j. If the RN is performing any other programming than a simple refill (changing the volume of medication) then the RN will call the on-call admistrator for a second RN review for accuracy.
- 2. There are risks of the proposed service related to dispensing and delivery of controlled substance medications. For example, Department of Health guidelines

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require that morphine equivalents be "delivered" directly to the ultimate user by an "agent" of a pharmacist. Are there other Pharmacy guideline requirements?

The pharmacy guidelines for storage and delivery of intrathecal medication are derived from the individual medication manufacturer. Most intrathecal medications are sensitive to light and extreme heat and or cold. For that reason the compounding pharmacy will ship the medication in amber, light resistant envelopes. The medication will be kept in a locked box until patient instillation. Also the medication syringe will be checked with the patient and the patient and or caregiver will confirm, their name, medication and dosage in the home prior to any implementation.

3. How will the medications be transported & obtained by the patient? For example, by the RN from the pharmacy delivered to the patient, by the RN from the physician's office delivered to the patient, or by the patient to pick-up directly from the pharmacy? What precautions are in place to prevent opioid diversion?

Opiod diversion will be evaluated by utilizing spot checks for RN evaluation, pt response to therapy and any trends with the RN and also by utilizing tamper proof caps to the vials. The pt will confirm that they syringe tamper proof cap in intact and that confirmation will be documented. IPM RN's will also be required to perform mandatory drug testing prior to hire and at regular intervals set by IPM.

4. How can patient issues be resolved before they transition into an emergent situation? How does a patient or caregiver know if there is an emergent situation? Who is responsible if the patient is admitted to a hospital? What actions will be taken to ensure that patients can be admitted by their personal physician to the nearest hospital?

The key to avoiding and or reducing emergent situations in regards to the patient is education. A large portion of every RN visit is education for the individual patient and the caregivers involved in care. The pump has internal alarms that sound for preset reasons. The patient and caregivers will be educated intensely on alarms, demonstrated the sounds to listen for, also on signs and symptoms of over/under dose, and on the need to have oral medications available in the home for emergency situations of under dosing. In addition to other topics, MRI safety and pt home safety, the patient and applicable caregivers will be educated on these above topics at every patient encounter. IMP feels that the better educated and more actively involved in the plan of care, the patient will obtain the highest possible results.

5. In terms of workforce issues, how will sick days and capacity issues be handled?

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In terms of workforce issues, sick days, leaves of absence and capacity issues will be handled on a short term basis by utilizing a traveling IPM RN that is licensed in the state of Tennessee. As the need arises for more hires, IPM will determine the best demographics for the pt census to be covered and recruit in those specific areas.

III. Administration of Home Service - Secure Medications

1. Compounding of drugs by contracted pharmacies - how or where are drugs mixed or are only FDA-approved, commercially available products used? If mixed, is manipulation or diversion of the product possible once mixed? What precautions will be taken by the contract pharmacy(s) to ensure preparation in a controlled, sterile environment? Is there information on infection rates in the home with IP services?

All drugs will be compounded directly pursuant to individual patient prescriptions in accordance with USP 797 standards, which are the federal regulations applicable to the compounding of infusion medications. The pharmacy with which we have chosen to contract is accredited by the Pharmacy Certification Accreditation Board (PCAB) which is a fundamental indicator of a compounding pharmacy's sterility and compliance with state and federal regulations (see Attachment – Exhibit 2.Additional Questions III.Administration of Home Service 1 for information regarding this accreditation). All powders mixed are from FDA-registered facilities and compounded in-house at the pharmacy location: 206-A Jacob's Run, Scott, LA 70583. Once compounded, diversion or manipulation of the product is not possible.

IPM currently has no data regarding rates of infection in the home as we do not yet have a sufficient patient caseload with which to compile such information.

2. Dosage is changed based on laboratory values. How will these values be taken and reported? For example, will the applicant's RN's draw blood and deliver it to laboratories? How is this process an improvement for the patient compared to performing this service in the physician practices that have existing arrangements with laboratory services?

This question is not relevant, the impression that physicians may adjust medications based upon lab values is not correct in regards to this therapy. Lab values are not used for therapeutic levels as in other systemic medications. The medication does not cross the blood brain barrier; therefore lab results would not be of a benefit. The ordering MD will assess the patient based on pain and or spasticity level, functional changes and overall general response to therapy.

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3. What safeguards are in place to ensure security of medications during transport to the home?

Upon receipt by the IPM RN, medications are immediately stored in a locked box in the trunk of the vehicle during transport to patient homes. The IPM RN is the only individual with access to this secure box.

Please refer to our attached policy regarding the safe transport of medication to patients (see Attachment – Exhibit 2.Additional Questions III.Administration of Home Service 3).

IV. Administration of Home Service - Payment for Service

Are there lower costs to the patient in providing this service in the home setting that can be passed on to commercial third parties?.

The lower costs to the patient for homecare management comes into play when the model eliminates most travel for pump management. The commercial third party payers are provided with the overall reduction of ER and un-necessary hospital admissions as part of IPM's proactive approach. IPM ultimately offers a more well rounded, more actively involved patient driving higher outcomes and lower overall costs.

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Attachment 9. Section C. Orderly Development. Item 7C

Pharmacy Service Agreement

This Pharmacy Services Agr	reement ("Agreement") is entered into	, ("Effective Date"),
	Pump Management, ("IPM") located at 200	Prosperity Place #102,
Knoxville, TN 37923 and		, located at
	("CONTRACTOR");

WHEREAS, CONTRACTOR is in the business of providing professional pharmacy services in jurisdictions where it is licensed;

WHEREAS, IPM is in the business of providing pharmacy and home infusion services to patients requiring intrathecal therapy in various jurisdictions;

WHEREAS, the parties desire that IPM shall use CONTRACTOR to all medication orders for patients of IPM when requested in jurisdictions where IPM is not licensed and/or requires assistance with said orders;

WHEREAS, the parties by this Agreement desire to set forth their various rights and responsibilities regarding the procedure and filling of medication orders;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties hereto agree as follows:

- 1. TERM. This agreement shall remain in full force and effect for an initial term of one year commencing on the Effective Date, and shall automatically be renewed unless either party delivers to the other party a written notice of intent to not to renew at least sixty (60) days prior to the end of each term, or any renewal thereof.
- 2. <u>TERMINATION</u>. This Agreement may be terminated with or without cause by either party at any time upon ninety (90) days prior written notice to the other party. The effective date of termination will be the first day of the month following the expiration of this ninety (90) day period.
- 3. <u>REPRESENTATIONS</u>. Contractor hereby agrees to:
- a. Dispense certain prescription medication orders (collectively "Services") to and for the clients of IPM as requested and instructed by **only** IPM's clinical staff. Services shall include delivery to authorized representatives of the individual patient or the patient and consultation with the appropriate dispensing physician, patient and/or IPM clinical staff.
- b. Provide services and be available to IPM on a normal workweek based on Monday through Friday from 8:30 am to 7:00 pm EST and be available 24 hours a day, 7 days per week for consultation.
- c. Bill independently for all pharmacy services provided.
- d. Maintain at all times throughout the Term of this Agreement a valid policy of insurance covering professional liability arising from the acts, omissions or negligence of CONTRACTOR, its agents, employees, designees or sub-contractors in an amount no less

than One Million Dollars (\$1,000,000) per claim or occurrence and Three Million Dollars (\$3,000,000) aggregate per year and One Hundred Thousand (\$100,000) in property damage coverage. Said polices shall name IPM as an additional insured and shall provide that the insurance company will not cancel said policy of insurance without giving IPM thirty (30) days advance written notice. CONTRACTOR's insurance shall be primary. On or before the Effective Date of this Agreement, CONTRACTOR shall provide to IPM a copy of such policy or certificate of insurance, indicating that CONTRACTOR has liability coverage (in at least the minimum coverage amounts set forth above) including coverage for any acts of malpractice if CONTRACTOR is a licensed professional.

f. CONTRACTOR agrees to be in compliance with the following:

1. Has all required current local, state, and federal pharmacy licensure subject to no restrictions or limitations for each jurisdiction in which a medication order is received and filled by CONTRACTOR for an IPM patient.

2. Has no prior record of noncompliance with any state or federal agency or board regulating the distribution or dispensing of pharmaceuticals that would prevent the

operation of this Agreement.

3. For all staff performing services hereunder, current state licensure subject to no restrictions or limitations.

4. Performs services in accordance with current standards for pharmaceutical services as promulgated by an accrediting organization approved by BHI.

5. Shall allow IPM to audit drug purchases for medications delivered to IPM patients and upon reasonable request provide documentation for drug purchases upon request.

4. <u>REPRESENTATIONS</u>. IPM agrees to provide records and information as is necessary for CONTRACTOR to dispense medications as requested by IPM ordering physicians and as permitted under applicable state and/or federal law, if any, and the rules and regulations promulgated there under and provides payment within sixty (60) days of the date of IPM's receipt of monthly billing statement.

5. JOINT REPRESENTATIONS. IPM and CONTRACTOR agree that:

- a. Nothing in this Agreement shall be used to constitute and obligation on the part of either party to make referrals to the other party. Further, nothing in this Agreement shall prohibit the parties from participating in health maintenance, insurance or third party payer programs as they so choose. This Agreement allows for the cost-effective use of resources and delivery of services and in no way constitutes a closed referral arrangement.
- b. The parties agree that each is at all times acting and performing as an independent contractor. Nothing in this Agreement shall be construed as creating a partnership, joint venture, or employment arrangement and no Party will have the power to obligate or bind the other Party in any manner whatsoever.
- c. Each party shall operate at all times in compliance with federal, state, and local laws, rules and regulations, the standards of Joint Commission (if applicable), and all currently

accepted methods and practices related to the provision of services contemplated hereunder.

- d. In order to facilitate the performance of this Agreement, each party may deem it necessary to disclose to the other certain proprietary and/or confidential information. Such information may include, without limitation, patient information, personnel information, financial information, market information, pricing information and service delivery information. Each party agrees to keep such information confidential. Each party agrees to maintain any information about the services provided by each party as propriety and confidential information and agree not to disseminate or disclose any information about the other to third parties.
- e. Any provisions of this Agreement creating obligations extending beyond the term of this Agreement will survive the expiration or termination of this Agreement, regardless of the reason of such termination.
- f. HIPAA To the extent applicable to this Agreement, the parties agree to comply with the applicable requirements of the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, as codified as 42 U.S.C.§1320d ("HIPAA") and any current and future regulations promulgated there under, including without limitation, the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Regulations"), the federal security standards as contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), and the federal standards for electronic transactions in 45 C.F.R. Parts 160 and 162 (the "Federal Transaction Standards") on or before their official compliance dates.
- g. All notices, consents or other communications which either party is required or may desire to give to the other under this Agreement shall be in writing and shall be given by personal delivery or by deposit, postage prepaid, in the United States mail, certified or registered mail, return receipt requested, addressed to the parties at their respective addresses set forth below:

If to CONTRACTOR:	Name:
	Address:
If to IPM:	Implanted Pump Management 200 Prosperity Place #102 Knoxville, TN 37923

- h. This Agreement may be executed in several counterparts, each of which will be deemed an original, which together will constitute but one and the same Agreement.
- i. The validity, interpretation and performance of this Agreement will be governed

according to the laws of the State of New Jersey, without reference to its conflict of laws principles. All parties agree to and hereby submit to the jurisdiction of the Superior Court of the State of New Jersey, County of Bergen.

- j. Each party warrants that it has the right to enter into this Agreement. Performance of the Agreement will not violate any agreement between it and any other third party.
- k. Any amendments to this Agreement will be effective only if in writing and signed by both parties. This Agreement constitutes the entire agreement of the parties hereto and supersedes all prior or contemporaneous agreements, undertakings and understanding of the parties in connection with the subject matter hereof.
- 1. No waiver of a breach of any provision of this Agreement will be construed to be a waiver of any other breach of this Agreement, whether of a similar or dissimilar nature.
- 6. NON COMPETITION OF INFUSION SERVICES. During the term of this Agreement and for a minimum period of three (3) years after termination of this Agreement or any additional period of time that protects the interests of IPM that is allowed by law, CONTRACTOR specifically agrees not to perform any such business IPM performs including, but not limited to any monitoring of patients, home care, and/or nursing services related to implanted pump therapies. Notwithstanding the foregoing, nothing in this provision shall be interpreted to restrict CONTRACTOR at any time from the filling of implanted pump therapy prescriptions in any way, with the exception of providing services to another homecare entity. It shall be deemed a breach of this provision if any patients serviced by IPM for implanted pump therapies during the term of this Agreement are subsequently serviced by another provider that is affiliated in any way with CONTRACTOR or its employees, directors, partners, owners or agents, directly or indirectly. If ownership of IPM is transferred or if IPM sells all or substantially all of its assets then this provision and full agreement will be transferable to the new entity. Further, CONTRACTOR agrees that during the term of this Agreement and for a period of five (5) years after termination of this Agreement or any such cessation of this agreement or employment for whatever reason, CONTRACTOR shall not solicit any employee of IPM during the term of this Agreement to enter into any employment agreement or independent contract arrangement with Contractor
- 7. EXCLUSIVITY. a. For so long as CONTRACTOR is capable of dispensing medication for IT therapy to certain patients of IPM, IPM agrees to provide all medication orders for the specific patients that are enrolled in the homecare program with IPM residing in States where CONTRACTOR is licensed unless IPM decides to fill patient prescriptions itself or in those jurisdictions that IPM receives referrals that request and/or are from pharmacies or physicians that require the pharmacy services to be used by another or currently used entity for that patient. IPM is not restricted in the performing pharmacy services in any manner during this Agreement and upon termination of this Agreement.
- b. Upon the commencement and through the term of this agreement, CONTRACTOR agrees that IPM shall be the exclusive home infusion provider that will be referred or recommended to patients, referral sources and/or physicians.

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8. <u>JOINT DISASTER RECOVERY</u>. Both parties agree to act as back-up pharmacy sites for each other in the event that one party experiences a Disaster situation. Both parties hereby agree to sign or contact governmental or quasi-governmental agency, any accreditation companies or entities to evidence such an agreement between the parties. In the event that one party requires emergency services as a result of a disaster whether a result of natural causes or other inability to function, the other party hereby agrees to reasonably perform and service the patients of the other at a cost to be mutually agreed upon.

In Witness whereof, we the undersigned, duly authorized representatives of the parties to this Agreement, hereinabove expressed, have entered into this Agreement without reservation and have read terms herein.

Dated:	Ву:	
	(Print Name and Title)	
	Implanted Pump Management	
	(Print Name and Title) CONTRACTOR:	

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Attachment – Exhibit 1.Additional Clarification IIV.Section C Orderly Development.Item 7

August 29, 2014 9:44 am



Licensing Standards

For

Home Health Agencies

N.J.A.C. 8:42

New Jersey Department of Health and Senior Services Certificate of Need and Acute Care Licensure Program

Effective Date: January 20, 2009 Expiration Date: December 19, 2013 Preparation Date: May 26, 2009

N.J.A.C. 8:42 TABLE OF CONTENTS

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SUBCHAPTER 1. SCOPE, PURPOSE AND DEFINITIONS

8:42-1.1 Scope; purpose

- (a) The rules in this chapter pertain to all home health agencies in the State of New Jersey.
- (b) The purpose of this chapter is to assure the provision of high quality home health care services to the residents of New Jersey in a coordinated and cost-effective manner.

8:42-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Activities of daily living (ADL)" means the functions or tasks for self-care which are performed either independently or with supervision or assistance. Activities of daily living include at least mobility, transferring, walking, grooming, bathing, dressing and undressing, eating, and toileting.

"Administrator" means a person who is administratively responsible and available for all aspects of facility operations, and:

- 1. Has a master's degree in administration or a health related field, and at least two years of supervisory or administrative experience in home health care or in a health care setting; or
- 2. Has a baccalaureate degree in administration or a health related field and four years of supervisory or administrative experience in home health care or in a health care setting.

"Advance directive" means a written statement of the patient's instructions and directions for health care in the event of future decision making incapacity in accordance with the New Jersey Advance Directives for Health Care Act, P.L. 1991, c.201. It may include a proxy directive, an instruction directive, or both.

"Available" means ready for immediate use (pertaining to equipment); capable of being reached (pertaining to personnel).

"Branch office" means a facility site from which services are provided to patients in their homes or place of residence; which is physically separate from the home health agency but shares administrative oversight and services; which meets all requirements for licensure; and which has available a nursing supervisor or alternate coverage by a registered professional nurse. When the nursing supervisor or alternate is not on the premises then there must be a licensed nurse on the premises when the facility is open to the public.

"Full-time" means a time period established by the facility as a full working week, as defined and specified in the facility's policies and procedures.

"Governing authority" means the organization, person, or persons designated to assume legal responsibility for the determination and implementation of policy and for the management, operation, and financial viability of the facility.

"Home health agency" or "agency" means a facility, which is licensed by the Department to provide preventive, rehabilitative, and therapeutic services to patients on a visiting basis in a place of residence used as a patient's home. All home health agencies shall provide at a minimum nursing, homemaker-home health aide, and physical therapy services and are eligible for Medicare-certification.

"Homemaker-home health aide" means a person who has completed a training program approved by the New Jersey Board of Nursing and who is so certified by that Board.

"Hours of operation" means normal business hours, during which the site is open to the public for business.

"Job description" means written specifications developed for each position in the facility, containing the qualifications, duties, competencies, responsibilities, and accountability required of employees in that position.

"Licensed nursing personnel" (licensed nurse) means registered professional nurses and practical (vocational) nurses licensed by the New Jersey Board of Nursing.

"Licensed practical nurse" means a person who is so licensed by the New Jersey Board of Nursing.

"Medication" means a drug or medicine as defined by the New Jersey Board of Pharmacy.

"Monitor" means to observe, watch, or check.

"Nursing supervisor" means a registered professional nurse who has at least one of the following qualifications:

- A bachelor of science degree in nursing and two years combined community health nursing and progressive professional responsibilities in community health nursing; or
- 2. Three years combined community health nursing and progressive professional responsibilities in community health nursing.

"Occupational therapist" means a person who is certified as an occupational therapist, and is registered by the National Board for Certification in Occupational Therapy and has at least one year of experience as an occupational therapist and complies with all New Jersey licensure requirements.

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Attachment - Exhibit 2.Additional Questions III.Administration of Home Service 3

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Policy For Transport and Delivery of Patient Medication

Purpose: To outline the mandated steps when the Registered Nurse (RN) transports patient medication to the individual patients home.

Policy: Each Implanted Pump Management (IPM) RN will adhere and comply with the procedure outlined in this policy.

Procedure:

- 1. The IPM RN will take only the required syringes from a locked box in his/her home required for the daily scheduled visits.
- 2. The IPM RN will verify the correct syringes have been selected for the scheduled visits
- 3. The IPM RN will transfer the syringes in an insulated bag from the RN home to the RN car and deposit the syringes in the locked box located in the vehicle trunk space.
- 4. The IPM RN will keep the key to the locked box on him/her at all times while performing daily activities. When home for the day the RN will place the key in a secure area.
- 5. The IPM RN will take one syringe per visit as indicated from MD orders out of the locked box located in the RN trunk space.
- 6. The IPM RN will wear no identifying "nurse" attire, i.e. scrubs, lab jacket, stethoscope.
- 7. The IPM RN will wear business casual dress attire as IPM policy dictates.
- 8. Upon instillation of medication, the IPM RN will re-check for clarity, sediment, volume, medication, patient name, concentration and daily dose with initial pump interrogation.
- 9. IPM RN will also ensure that safety cap has not been compromised.
- 10. In the event of the safety cap being compromised the IPM RN will not use the medication and follow the IPM policy for potentially contaminated syringe.

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AFFIDAVIT

COUNTY OF Passaic

Conne Adamek being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, et seq., and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

Sworn to and subscribed before me this 28th day of August (Month) 2014 a Notary

Public in and for the County/State of Passaic / New Jersey

NOTARY PUBLIC

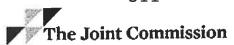
My commission expires 12-

12-29-2016 [(Month/Day)

Z016 (Year)

NADIA SALMON
Notary Public
New Jersey
My Commission Expires 12-29-16

August 29, 2014 9:44 am



July 18, 2014

Melissa Hess, RN Director of Nursing Implanted Pump Management LLC 2200 N Commerce Parkway, Suite 253 Weston, FL 33326 Joint Commission ID #: 557274
Program: Home Care Accreditation
Accreditation Activity: Early Survey - Option

Accreditation Activity Completed: 07/18/2014

Dear Ms. Hess:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Preliminary Accreditation for all services surveyed under the applicable manual(s) noted below:

Comprehensive Accreditation Manual for Home Care

This accreditation cycle is effective beginning July 19, 2014. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 6 months.

Please visit <u>Quality Check®</u> on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Mark G.Pelletier, RN, MS

Chief Operating Officer

Division of Accreditation and Certification Operations

ark Pelletin

September 16, 2014

9:49 am



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364/Fax:615/532-9940

September 15, 2014

Melissa Hess, RN
Director of Nursing
Implanted Pump Management
200 Prosperity Place #102
Knoxville, TN 37923

RE:

Certificate of Need Application CN1407-027

Implanted Pump Management

Dear Ms. Hess,

This will acknowledge our August 29, 2014 receipt of your 3rd supplemental response pertaining to your application for a Certificate of Need for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services to patients residing in all 95 Tennessee counties from its parent office located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Towards the end of this letter you will find information regarding "deemed complete" or "deemed incomplete" status of an application and a "deemed void" date. If this application is not complete prior to that date, it will be deemed void. In order to help expedite the review process, please resubmit all required information in the format described and respond to our initial questions in triplicate, with affidavit by 4:00 p.m. Tuesday, September 9, 2014. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section B, Project Description, Item 1

On page 20 of the 8/29/14 response, the applicant states that it plans to provide IP services at other third party facilities such as long term care facilities and hospitals.

Melissa Hess September 15, 2014 Page 2

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Please describe the responsibilities of the parties and provide a copy of a draft working agreement or similar arrangement to document same.

IPM intends to provide all nursing services related to intrathecal infusion therapy. IPM will only be responsible for all aspects of care directly related to the refill and maintenance of the infusion pump and will coordinate this care with third-party facilities as necessary in order to provide services to patients at their home, school, work, hospital, or nursing facility.

Please see Attachment 1.Section B Project Description.Item 1 for a copy of our Care Coordination Contract template.

2. Section B, Project Description, Item II.C.8

The response on page 22 is noted. In addition to calling 911 and transfer to an ED, what arrangements will be coordinated with the patient's managing physician regarding admission to area hospitals in emergent situations?

The coordination of emergency situations with patients will be done directly with the patients ordering physician. IPM will only assist in facilitating or recommending emergency care if required. If the recommendation is made by IPM, or any concerns are present based upon assessment findings and or phone triaging, the ordering physician will be made aware regardless of the time of day. IPM will implement any recommendations without knowledge of the ordering MD.

3. Section C, Need, Item 1 (Project Specific Criteria)

<u>Item 5A</u> — As noted, it is important to note that this criterion cannot be met without letters from physicians, or other providers closely associated with them such as hospitals that documents a need for the service. In addition, as a suggestion, testimonials by existing HHAs, pain clinics and long term care facilities could also be submitted to document the need for the proposed IP home infusion. Please provide the documentation requested in the application and supplemental questionnaires.

4. Section C, Need, Item 5

In earlier correspondence the applicant states that there are 2 existing home health agencies in Tennessee that provide IP home infusion therapy services, although the extent was believed to be minimal. Please identify the utilization of the 2 HHAs such as # of skilled nursing visits for the most recent 12 month period available. Identify the name of the agency and visits by county, if known.

Earlier correspondence had incorrectly stated that Intrepid Home Health provided intrathecal home infusion therapy services. Upon further investigation it was found that they, in fact, do not – Intrepid provides alternate types of home infusion therapy.

The only home health agency that is able to provide intrathecal home infusion services within the state of Tennessee is Camellia Home Health. According to Angie Hyatt, their Director of Nursing for the Knoxville office, Camellia has never provided these specific services to any of their Tennessee patients as of yet. Therefore, IPM

Supplemental #4
September 16, 2014

Melissa Hess September 15, 2014 Page 3

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will, once licensed, be the first home health agency within the state to provide these services.

The following utilizations were taken from Camellia's 2013 Joint Annual Report, the most current report available (please see Attachment 4.Section C Need.Item 5). The total number of patients served by Camellia Home Health of Tennessee in 2013 was 1,716. The unduplicated patient census for the first day of the 2013 reporting period was 453. Total revenue from this period from all sources is \$15,731,719. The total number of skilled nursing care visits for this period is 19,479 (out of 58,202 total visits) and the total number of hours of skilled nursing care provided is 128,013 (out of 221,966 total hours). Camellia reported servicing patients within the following 22 counties for this period: Anderson, Blount, Campbell, Claiborne, Cocke, Cumberland, Grainger, Hamblen, Hancock, Hawkins, Jefferson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Rhea, Roane, Scott, Sevier, and Union.

Please reference Camellia's utilization in the below table.

1 10000 1010101	
Skilled Nursing Visits	19,479
Total Visits	58,202

Tennessee County	Camellia Patients per county
Anderson	92
Bedford	1
Benton	X X
Blount'	40
Bradley	
Campbell	77
Cannon	
Carroll	
Carter	
Cheatham	
Chester	
Claiborne	12
Clay	
Cocke	39
Coffee	
Crockett	
Cumberland	60
Davidson	
Decatur	
DeKalb	
Dickson	
Dyer	
Fayette	

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Grainger 17 Greene Crundy	
Greene Grundy	
Grundy	
Hamblen 162	
Hamilton	
Hancock 6	
Hawkins 13	
Haywood	
Henderson	
Henry	
Hickman	
Houston	
Humphreys	
Jackson	
Jefferson 68	
Johnson	
Knox 484	
Lake	
Lauderdale	
Lawrence	
Lewis	
Lincoln	
Loudon 103	
McMinn 162	
McNairy	
Macon	
Madison	
Marion	
Marshall	
Maury	
Meigs 23	
Monroe 70	ř.
Montgomery	
Moore	
Morgan 16	
Obion	

September 16, 2014 9:49 am

Melissa Hess September 15, 2014 Page 5

Overton	
Perry	
Pickett	
Polk	
Putnam	
Rhea	26
Roane	122
Robertson	
Rutherford	
Scott	4
Sequatchie	
Sevier	108
Shelby	
Smith	
Stewart	
Sullivan	
Sumner	
Tipton	
Trousdale	
Unicoi	
Union	12
Van Buren	
Warren	
Washington	
Wayne	
Weakley	
White	
Williamson	
Wilson	
Tennessee Total	1,716

5. Section C, Need, Item 6 and Section C, Economic Feasibility, Item 8

Please provide an estimate for the percentage of 1,440 projected visits in Year 1 of the project that might apply to visits by IPM staff at other third party facilities such as hospitals and long term care facilities.

The applicant estimates utilization by patients with commercial insurance at 99% of revenues. Based on this, the financial viability of the project is highly dependent on this source of revenue. As a new service provider in Tennessee, please document the interest in the proposed IP home infusion service by commercial or managed care plans in the service area.

Melissa Hess September 15, 2014 Page 6

September 16, 2014 9:49 am

The estimated visits of 1,440 projected for year one are completely independent of any visits of emergency nature. The estimated year 1 visits are solely for implanted pump refilling, titrating and assessment required for proper and effective pump management.

6. Section C, Orderly Development, Item 2

The applicant's response is noted. Please also describe consideration given to establishing an HHA limited to IP home infusion services in those counties where the target populations are highest (MS, CP and chronic pain).

The consideration and decision to create the services in the state of Tennessee was made due to the fact that the proposed services are not currently available to the majority of the state and only limited in before mentioned counties. As IPM will grow, more focus may be required in certain counties where the highest prevalence of MS, CP and chronic pain exist. The proposed IPM structure will only require additional staffing and trained professionals to accomplish this goal.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60th) day after written notification is September 23, 2014. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the <u>next review cycle</u>, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. → 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete

September 16, 2014 9:49 am

Melissa Hess September 15, 2014 Page 7

and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please contact this office.

Sincerely,

Jeff Grimm HSD Examiner Enclosure 320

SUPPLEMENTAL #4
September 16, 2014
9:49 am

Attachment 1.Section B Project Description.Item 1

COPY

ADDITIONAL INFORMATION

Supplemental -4

Implanted Pump Management

CN1407-027

Rice E. As endell, MI I

Khin W. C. MD

Richard A. Berloman MD

THE UPS STORE HERMITAGE

SUPPLEMENTAL #4

322

September 23, 2014

10:00 am

William R. Schooley,

MD Michael J. Schlower, MD Jacob P. Schwass, MD

Neurosurgical Associates 2400 Patterson Street, Suite 319

Nashville, Tennessee 37203

Phone: (615) 986-1256

Fax: (615) 383-08

September 19, 2014

To Whom It May Concern:

This intent of this letter is to request an expansion of intrahthecal home care tervices in the state of Tennessee. The current home health agency structure established in Tenness :: does not efficiently provide intrathecal home care services to the state of Tennessee.

It is my opinic a that the expansion of intrathecal home care services in the sate of Tennessee would be beneficial to the intrathecal pump patient population.

Sincerely,

William R. Schooley, M.D.

-Sarellice Locations -

"Ashland City Carden - Clarksville - Cookeville - Cook Springs - Dickson - Gallatio - Hermanys - Legenceburg - Manchester -

"Mr. Juliet Minfrensbeim "Shelbyville - Spring Hill - Smithville - Smyrna - Winchester - Vin Juney -

323
September 23, 2014
10:00 am
Additional Information – Supplemental 4 – CN1407-027

September 23, 2014 10:00 am



THE SHURDERSWELLT WERE SUITE THE TELL THE MILLE. THE STORY | WWW COSTICLE TOM

To Whom it May Concern:

The intent of this letter is to request an expansion of intrathecal home care services in the state of Tennessee. The current home health agency structure established in Tennessee does not efficiently provide intrathocal home care services to the patients of Tennessee. It is my opinion that the expansion of intrathecal home care services in the state of Tennessee would be beneficial to the intrathecal pump patient population.

Sincerely

Humana Military.



Provider

Provider Education

Self Service

TRICARE Information

Claims

Find a Provider

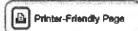
Billing and Filing Guidelines

Claims Processing Standards

ICD-10 Readiness

Home Infusion

Provider Office



Adjust Text Size:



Home Infusion Injectables Guidelines

The following educational information is provided to facilitate timely and accurate claim filing for reduction of billing errors, rework of claims, and prompt payment of home infusion therapy services for TRICARE.

TRICARE Policy (TRM Chapter 3, Section 6, II, B, 1) requires the use of appropriate "J" HCPCS codes and the specific NDC # for pricing using 95% of the AWP.

Recurring billing errors have been identified and are listed here:

- Use of Miscellaneous "J" codes (e.g., J3490, J3590, and J9999) when specific "J" codes are available.
- 2. Non-compliance with billing guidelines (e.g., paper CMS-1500 or electronic HIPAA 837).
- 3. Entry of NDC quantities in the HCPCS quantity field.
- 4. Failure to provide the NDC#.
- 5. Failure to provide the NDC Unit of Measure.
- 6. Failure to provide the NDC Quantity.

Instructions below should improve your timely and accurate claims resolution and payment:

A. NDC field

Some NDCs may be in a 10-digit format. The chart below illustrates how to convert the code into 11-digits. (Hyphens in the example below are for illustration only.)

10-Digit Format on Package	10-Digit Format on Example	11-Digit Format	11-Digit Format Example
4-4-2	9999-9999-99	5-4-2	099999-9999-99
5-3-2	99999-999-99	5-4-2	99999-0999-99
5-4-1	99999-9999-9	5-4-2	99999-9999-09

B. NDC Units/Quantity field

The quantity of each submitted NDC must be a numeric value greater than zero. In most cases, the NDC quantity will be different from the HCPCS billed units. To determine the correct NDC quantity, refer to the data column titled CF (conversion factor) on the Noridian Crosswalk Table. This table is updated monthly by CMS.

Identify your "J" code and correlating NDC# for your combination record, divide the number of billed HCPCS units by the CF; and enter the resulting number as the NDC Quantity.

NOTE (1): Whenever a Miscellaneous "J" code is used, the CF is NOT valid. In these cases your entry of the NDC Quantity is the sole source of quantity to be priced based on the AWP. NOTE (2): "J" code HCPCS Quantities must always be stated in "whole" numbers. NDC Quantities

7. INSURANCE 326

IPM shall maintain general and professional liability insurance with a September 16, 2014 \$1,000,000 per occurrence and \$3,000,000 in the aggregate, and shall supply the **R49 rate** ource with a certificate of insurance evidencing such coverage and shall provide thirty (30) days' written notice prior to the cancellation of any such policies.

8. ASSIGNMENT

Neither party may assign its rights or obligations with respect to this Agreement without the prior written approval of the other party; provided, however, that such an assignment may be made to an entity which is related by virtue of a common parent corporation or which is directly or indirectly, wholly owned or controlled by the same entity as the assigning party.

9. INDEMNIFICATION

Each party agrees to indemnify the other, their affiliates and their respective officers, directors, employees and agents against, and hold the same harmless from, all liability, losses, damages, obligations, judgments, claims, causes of action and expenses associated therewith (including settlements, judgments court costs and attorney's fees) resulting from or arising out of, directly or indirectly, and any negligent or intentional act or omission or any failure to perform any obligation undertaken in or any covenant made under this Agreement. Upon notice, each party shall resist and defend at its own expense, and by counsel reasonably satisfactory to the other, any such claim or action.

IPM agrees to indemnify and hold the Referral Source harmless against and from any and all claims of the patients that arise from the infusion, programming or care provided by IPM, its affiliates, contractors and/or agents. IPM will be responsible for infusion and monitoring as set forth above. The Referral Source and/or the physicians providing the prescription are solely responsible for medication errors not related to IPM-provided infusion therapies. The Referral Sources and/or the physicians agree to indemnify and hold IPM harmless against and from any and all claims of the patients that arise from the incorrect prescription or any such medication order and/or prescription error not related to IPM-provided infusion therapies.

10. INDEPENDENT CONTRACTOR

The parties agree that each is at all times acting and performing as an independent contractor. Nothing in this Agreement shall be construed as creating a partnership, joint venture, or employment arrangement and no Party will have the power to obligate or bind the other Party in any manner whatsoever. Each party may contract/subcontract with multiple providers or agencies at anytime.

11. EQUAL EMPLOYMENT OPPORTUNITY POLICY

The parties agree, if applicable, to comply with the Equal Employment Opportunity policies provided in Executive Order 11246 (as set forth in 41 CFR § 60-1.4(a) and incorporated herein by reference), the Rehabilitation Act of 1973 (as set forth in 41 CFR § 60-741.5(a) and incorporated herein by reference), and the Vietnam Era Veterans Readjustment Assistance Act (as set forth in 41 CFR § 60-250.4 and incorporated herein by reference).

12. LICENSURE AND CERTIFICATION

Each party shall operate at all times in compliance with federal, state, and local laws, rules and regulations, the standards of Joint Commission (if applicable), and all currently accepted methods and practices related to the provision of services contemplated hereunder.

13. CONFIDENTIALITY AND NON-SOLICITATION

In order to facilitate the performance of this Agreement, each party may deem it necessary to disclose to the other certain proprietary and/or confidential information. Such information may include, without limitation, patient information, personnel information, financial information, market information, pricing information and service delivery information. Each party agrees to keep such information confidential. Each party agrees to maintain any information about the services provided by each party as propriety and confidential information and agree not to disseminate or disclose any information about the other to third parties.

During the term of this agreement and for a period of five (5) years thereafter the Referral Source will not in conjunction with any other person, firm or entity solicit, entice or attempt to solicit or entice or

employ any person that is or was employed with IPSM2 7

September 16, 2014

Referral Source will not on behalf of or in conjunction with any other p9:49 tarm or entity, to solicit, entice or attempt to solicit or entice any principal or owner of IPM to sever or alter its/his relationship with IPM to the detriment of IPM.

14. SURVIVAL

Any provisions of this Agreement creating obligations extending beyond the term of this Agreement will survive the expiration or termination of this Agreement, regardless of the reason of such termination.

15. HIPAA

To the extent applicable to this Agreement, the parties agree to comply with the applicable requirements of the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, as codified as 42 U.S.C.§1320d ("HIPAA") and any current and future regulations promulgated thereunder, including without limitation, the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Regulations"), the federal security standards as contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), and the federal standards for electronic transactions in 45 C.F.R. Parts 160 and 162 (the "Federal Transaction Standards") on or before their official compliance dates. The parties agree not to use or further disclose any protected health information, as defined in 45 C.F.R. §164.501, or individually identifiable health information, as defined in 42 U.S.C. § 1320(d) (collectively, the "Protected Health Information"), concerning a patient other than as permitted by this Agreement, the requirements of HIPAA, and the regulations promulgated under HIPAA including, without limitation, the Federal Privacy Regulations, the Federal Security Regulations, and the Federal; Transaction Standards. Additionally, on or before the official date of compliance, shall enter into a mutually agreeable business associate agreement with Referral Source, if required under the Federal Privacy Regulations agreeing to safeguard Protected Health Information, and upon its execution, such agreement shall be attached to this Agreement and incorporated herein as an addendum. IPM will fully adhere to the requirements under HIPAA procedure and will have all referred patients sign the proper HIPAA disclosure/consent forms at the admission of treatment and such is a permanent part of the patient's medical chart.

16. ELECTRONIC STORAGE OF AGREEMENT

The parties agree that the original of the Agreement, including the signature pages, may be scanned and stored in a computer database or similar device, and that any printout or other output which is readable, and which is shown to be an accurate reproduction of the original of this document, may be used for any purpose just as if it were the original Agreement, including the proof of the content of the original writing and the signing of the original writing.

17. NOTICES

All notices, consents or other communications which either party is required or may desire to give to the other under this Agreement shall be in writing and shall be given by personal delivery or by deposit, postage prepaid, in the United States mail, certified or registered mail, return receipt requested, addressed to the parties at their respective addresses set forth below:

If to Referral Source:	
If to IPM:	Implanted Pump Management LLC 200 Prosperity Place Knoxville, TN 37923

18. GENERAL PROVISIONS

This Agreement may be executed in several counterparts, each of which will be deemed an original, which together will constitute but one and the same Agreement.

The validity, interpretation and performance of this Agreement will be governed according to the laws of the State of Tennessee, without reference to its conflict of laws principles. All parties agree to and hereby submit to the jurisdiction of the Superior Court of the State of Tennessee, County of Knox.

Each party warrants that it has the right to 3 2 into this Agreement.

Performance of the Agreement will not violate any agreement between it as a property 16, 2014

Corporation warrants that it owns the Corporation represented in this Agreement does not violate any other agreement or understanding by which Corporation is bound. Corporation further warrants that it is unaware of any information that would render any of the claims of its Confidential Information invalid or unenforceable.

Corporation further warrants that, to the best of its knowledge, there is no third party ownership claims to the Corporation and that Corporation has taken all measures to have employees and contractors assign such intellectual property rights to Corporation.

Contracting parties must be clearly identified by using the contracting party's full legal name and state of legal incorporation or registration.

Any amendments to this Agreement will be effective only if in writing and signed by both parties.

This Agreement constitutes the entire agreement of the parties hereto and supersedes all prior or contemporaneous agreements, undertakings and understanding of the parties in connection with the subject matter hereof.

No waiver of a breach of any provision of this Agreement will be construed to be a waiver of any other breach of this Agreement, whether of a similar or dissimilar nature.

Dated:	By:	THE SECTION AND ADDRESS.
Dated:	Ву:	
	Roy C. Putrino, CEO	
	Implanted Pump Man	agement LLC

CARE COORDISATION CONTRACT

September 16, 2014

This Agreement made this	day of _	_2014, between	Implanted	P9149/amgement	LLC
("IPM") located at 200 Prosperity				("Referral Sou	ırce")
located at	·				

Recitals

- A. IPM or its affiliates, contractors and/or agents, is licensed to perform nursing and pharmacy duties in the jurisdiction of the Referral Source and/or its patients.
- B. IPM and the Referral Source are fully insured to perform their respective services set forth herein.
- C. The Referral Source desires to refer certain patients in need of infusion therapy and monitoring for an intrathecal implanted pump.

The parties hereby agree to the following:

1. SERVICES

IPM will be responsible for refilling, titration and monitoring of the Medtronic pump patients. IPM will supply the nursing services associated with infusion therapy. IPM will handle all issues associated with the pump and field all patient calls. The patient will be directed to call IPM staff RNs when in need of dose titration or for any other issues related to infusion therapy. IPM will coordinate all refill dates with the patient and schedule accordingly with the Referral Source. All reports, nursing notes and telemetry results will be mailed to the prescribing physician after each visit. IPM is able to go to the patient's home, school, work, hospital, nursing facility or other location to refill the pump.

2. NO PAYMENT FOR REFERRAL

It is specifically agreed to by IPM and the Referral Source that this Agreement does not allow for remuneration of any kind for any patient referrals. No monetary, as well as other payments have or will be exchanged for referrals as contemplated by the parties. Payments such as kick-backs in any form are prohibited by any person directly or indirectly from each party.

3. NO PRIOR AGREEMENT

This Agreement embodies the entire understanding between the Parties relating to the subject of this Agreement, and there are no related prior representations or agreements not specified herein.

4. NO CHANGES

No change in this Agreement will be binding on either Party unless approved in writing by its authorized representative.

5. ENFORCEABILITY

If any provision of this Agreement is determined to be invalid, illegal or unenforceable for any reason, that provision will be reformed to the maximum extent permitted to preserve the Parties' original intent, failing which, it will be severed from this Agreement with the balance of the Agreement continuing in full force and effect. Such occurrence will not have the effect of rendering the provision in question invalid in any other jurisdiction or in any other case or circumstances, or of rendering invalid any other provisions constrained in this Agreement to the extent that such other provisions are not themselves actually in conflict with any applicable law.

6. TERMINATION

Either party may terminate with or without cause this Agreement at any time upon ninety (90) days prior written notice to the other party. The effective date of termination will be the first day of the month following the expiration of this ninety (90) day period. This Agreement may automatically renew upon the expiration of the Agreement.

September 16, 2014 9:49 am

Attachment 4.Section C Need.Item 5

can be stated in up to three places to the right of the decimal. **September 23,020114** is "rounded" to the nearest "whole" number.

C. NDC Measurement (Package/Unit Indicator) field

The unit of measurement (UOM) for each NDC must be submitted. Noridian Crosswalk Table assumes the conversion of Units NOT Packages. If using the conversion factor on the Noridian Crosswalk Table, the UOM should always be submitted as "Units". (UN, ML, or GR for electronic HIPAA 837 and "U" for paper CMS-1500 claims).

If you are one of the many providers enjoying the benefits of electronic claim filing, the following data elements should be used to submit the NDC information in the HIPAA-standard ASC X12 837 claims format:

LIN03-product/srevic-NDC (11-digit format).

CTP04-NDC units (must be numeric value greater than 0 (up to 3 decimal places allowed).

 CTP05-1-NDC unit of measurement (UN, ML, GR, or F2). The UN, ML, and GR are priced as units. The F2 is priced as a package. However, you should avoid using the F2 value if possible.

Some things to remember when filling claims for home infusion medications:

 Make sure the NDC number, units, and unit of measurement are listed on the gray line above the HCPCS code if you are filing using a CMS-1500 claim form.

Report the NDC number in the 11-digit format.

 Use the Noridian Crosswalk Table to convert the HCPCS units into NDC units: submit the UOM as units (UN, ML, or GR).

Place of service must be "home".

 If Infusion therapy is performed in an Ambulatory Infusion Suite, place of service must be "office" and the HCPCS must be submitted with modifier "SS"

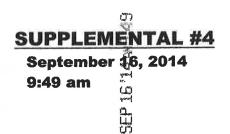
Back to Top

Last Update: September 26, 2013

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Humana Veterans | Careers | Site Map | Search

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AFFIDAVIT



STATE OF NEW TERSEY

COUNTY OF PASSAIC

being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, et seq., and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

SIGNATURE/TITLE

Sworn to and subscribed before me this



Public in and for the County/State of



NOTARY PUBLIC

My commission expires





NADIA SALMON Notary Public New Jersey My Commission Expires 12-29-16



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 **www.tn.gov/hsda** Phone: 615-741-2364 Fax: 615-741-9884

October 1, 2014

Melissa Hess, Director of Nursing Implanted Pump Management 200 Prosperity Place, #102 Knoxville, TN 37923

RE: Certificate of Need Application -- Implanted Pump Management, LLC - CN1407-027

Dear Ms. Hess:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The parent office will be located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932. There are no branch offices proposed for this project. The service area includes all 95 counties in Tennessee. Project cost is \$13,038.00.

Please be advised that your application is now considered to be complete by this office. Your application is being forwarded to the Tennessee Department of Health and/or its representative for review.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on October 1, 2014. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on December 17, 2014.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Malaine M. Hill /W=

Melanie M. Hill Executive Director

MMH:mab

cc: Trent Sansing, CON Director, Division of Health Statistics



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO:

Trent Sansing, CON Director

Office of Policy, Planning and Assessment

Division of Health Statistics

Andrew Johnson Tower, 2nd Floor 710 James Robertson Parkway Nashville, Tennessee 37243

FROM:

Melanie M. Hill MMH/M=

Executive Director

DATE:

October 1, 2014

RE:

Certificate of Need Application

Implanted Pump Management, LLC - CN1407-027

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on October 1, 2014 and end on December 1, 2014.

Should there be any questions regarding this application or the review cycle, please contact this office.

MMH:mab

Enclosure

cc: Melissa Hess, Director of Nursing



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 **www.tn.gov/hsda** Phone: 615-741-2364 Fax: 615-741-9884

November 25, 2014

Melissa Hess, Director of Nursing Implanted Pump Management 200 Prosperity Place, #102 Knoxville, TN 37923

RE:

Implanted Pump Management, LLC - Certificate of Need CN1407-027

The establishment of a home care organization and initiation of home health services limited to intrathecal pump services to be provided within all 95 counties in the State from 1 office located at 200 Prosperity Place #102, Knoxville, TN 37923.

Dear Ms. Hess:

This is to notify you that the referenced application that was originally scheduled to be acted upon by the Agency on December 17, 2014 is being deferred for 90 days at the Department of Health's request. The application will be rescheduled for action at the March 25, 2015 Agency meeting.

A copy of the department's deferral request is attached.

and Mele

Sincerely,

Melanie M. Hill Executive Director

Enclosure



STATE OF TENNESSEE DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH COMMISSIONER

BILL HASLAM GOVERNOR

November 24, 2014

Ms. Melanie Hill, Executive Director Health Services and Development Agency Andrew Jackson Building Deaderick Street Nashville, TN 37243

HAND-DELIVERED

Re: Certificate of Need Application No. <u>CN1407-027 filed by Implanted Pump Management LLC</u>

Dear Director Hill:

The Tennessee Department of Health (TDH) has been reviewing the above-referenced application for a Certificate of Need (CON) that is set to be heard on December 17, 2014. TDH has devoted a great deal of time to its review but finds that issues that have arisen regarding TDH's regulatory responsibilities require more effort, and thus more time, before its report to the Health Services and Development Agency can be finalized. In order to provide sufficient time for TDH to complete its work, TDH requests that the HSDA defer hearing this CON application for 90 days, as is permitted by statute.

THD also requests that any other CON applications for similar services received by HSDA also be so deferred.

Sincerely,

John J. Dreyzehner, MD, MPH, ACOEM

Commissioner

JJD/JO/tls

5th Floor, Andrew Johnson Tower 710 James Robertson Parkway * Nashville, TN 37243 (615) 741-3111 * www.tn.gov/health



STATE OF TENNESSEE

DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH COMMISSIONER

BILL HASLAM GOVERNOR

November 24, 2014

Ms. Melanie Hill, Executive Director Health Services and Development Agency Andrew Jackson Building Deaderick Street Nashville, TN 37243

HAND-DELIVERED

Re: Certificate of Need Application No. $\underline{CN1407-027}$ filed by Implanted Pump $\underline{Management\ LLC}$

Dear Director Hill:

The Tennessee Department of Health (TDH) has been reviewing the above-referenced application for a Certificate of Need (CON) that is set to be heard on December 17, 2014. TDH has devoted a great deal of time to its review but finds that issues that have arisen regarding TDH's regulatory responsibilities require more effort, and thus more time, before its report to the Health Services and Development Agency can be finalized. In order to provide sufficient time for TDH to complete its work, TDH requests that the HSDA defer hearing this CON application for 90 days, as is permitted by statute.

THD also requests that any other CON applications for similar services received by HSDA also be so deferred.

Sincerely,

John J. Dreyzehner, MD, MPH, FACOEM

Commissioner

JJD/JO/tls



STATE OF TENNESSEE

DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH COMMISSIONER

BILL HASLAM GOVERNOR

November 24, 2014

Ms. Melanie Hill, Executive Director Health Services and Development Agency Andrew Jackson Building Deaderick Street Nashville, TN 37243

HAND-DELIVERED

Re: Certificate of Need Application No. $\underline{CN1407-027}$ filed by Implanted Pump $\underline{Management\ LLC}$

Dear Director Hill:

The Tennessee Department of Health (TDH) has been reviewing the above-referenced application for a Certificate of Need (CON) that is set to be heard on December 17, 2014. TDH has devoted a great deal of time to its review but finds that issues that have arisen regarding TDH's regulatory responsibilities require more effort, and thus more time, before its report to the Health Services and Development Agency can be finalized. In order to provide sufficient time for TDH to complete its work, TDH requests that the HSDA defer hearing this CON application for 90 days, as is permitted by statute.

THD also requests that any other CON applications for similar services received by HSDA also be so deferred.

Sincerely,

John J. Dreyzehner, MD, MPH, FACOEM

Commissioner

JJD/JO/tls

FARRIS BOBANGO, PLC

ATTORNEYS AT LAW

Nashville · Memphis

HISTORIC CASTNER-KNOTT BUILDING 618 CHURCH STREET, SUITE 300 NASHVILLE, TENNESSEE 37219

(615) 726-1200 telephone · (615) 726-1776 facsimile

Rachel C. Nelley rnelley@farris-law.com

Direct Dial: (615) 687-4231

Deleg

February 4, 2015

Ms. Melanie M. Hill Executive Director Health Services and Development Agency Andrew Jackson, 9th Floor 502 Deaderick Street Nashville, TN 37243

RE: Implanted Pump Management, LLC - CN 1407-027

Dear Ms. Hill:

Please be advised that this firm has been asked to represent the above-referenced applicant in connection with the presentation of its certificate of need application. I understand that the application is due to be considered at the Agency's March 25, 2015 meeting.

I would appreciate it if you would forward me a copy of the Department of Health's report summarizing its review of the application at your earliest convenience.

Sincerely

Rachel C. Nelley Attorney-at-law

RCN/

cc: Melissa Hess, RN, BSN, Implanted Pump Management LLC

HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING MARCH 25, 2015 APPLICATION SUMMARY

NAME OF PROJECT: Implanted Pump Management, LLC

PROJECT NUMBER: CN1407-027

ADDRESS: 200 Prosperity Place, Suite 102

Knoxville, (Knox County), Tennessee 37923

LEGAL OWNER: Implanted Pump Management, LLC

1401 Valley Road

Wayne, New Jersey 07470

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Melissa Hess, Director of Nursing

Implanted Pump Management, LLC

200 Prosperity Place, Suite 102 Knoxville, Tennessee 37923

(201) 475-9635

DATE FILED: July 3, 2014

PROJECT COST: \$13,038

FINANCING: Cash Reserves

PURPOSE FOR FILING: Establishment of a home care organization and the

initiation of specialized home health services limited

to intrathecal pump services.

DESCRIPTION:

Implanted Pump Management, LLC (IPM) is requesting approval to establish a home care organization and provide specialized skilled nursing services for patients with surgically implanted intrathecal pumps under physician's orders. The applicant's proposed specialized home health service will be contractually supported by Basic Home Infusion Pharmacy located at 1401 Valley Road in Wayne, New Jersey; Intrathecal Compounding Specialists, LLC (ICS) located at 206A Jacob's Run in Scott, Louisiana; and possibly other qualified pharmacies to

be selected by the applicant as necessary. Both named pharmacies hold active Tennessee licenses issued by the Tennessee Department of Health. The applicant states that the pharmacies will be contracted to provide medication compounding, processing of physician orders, medication dose titrations and changes, and consultation with the appropriate dispensing physician, patient and IPM clinical staff. An overview of the nature and scope of the services provided by the applicant and the contracted pharmacy (s) is summarized on pages 10 and 11 of the application, pages 22-23 of Supplemental 1 and page 8 of Supplemental 2.

The applicant proposes serving all 95 Tennessee Counties from a home office located at 200 Prosperity Place, Suite 102 in Knoxville (Knox County), Tennessee.

Important Note to Agency Members: Following HSDA completeness review ending September 2014, the application was submitted to TDH for mandatory 60 day licensing agency review in accordance with HSDA Rules. Subsequently, John Dreyzehner, MD, MPH, Commissioner, Tennessee Department of Health, submitted a letter on November 24, 2014 to Melanie Hill, Executive Director, HSDA, requesting that the Agency's Board defer hearing the application in December 2014 by granting an additional 90 days before hearing the application in order to finalize its review of the project. HSDA approved the request and placed the application on the agenda for the March 25, 2015 Agency meeting. Dr. Dreyzehner's letter follows this summary.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

- 1. The need for home health agencies/services shall be determined on a county by county basis.
- 2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.
 - The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
- 3. Using recognized population sources, projections for four years into the future will be used.
- 4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

The applicant states that the specialized nature of the proposed skilled nursing service and the lack of comparable utilization data from existing agencies impact the ability to provide an estimate of need for specialty infusion therapy services. Following Steps 1-4 above, the Department of Health report that is based on 2013 "Final" data indicates that 102,503 residents of the applicant's proposed 95 county service area will need home health care in 2018; however approximately 184,157 patients are projected to be served in 2018 by existing home health organizations resulting in a net excess or surplus of (81,654).

It appears that this application does <u>not</u> meet the criterion.

5. Documentation from referral sources:

a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

During initial staff review of the application, the applicant provided letters of support in the application from two patients that currently have implanted intrathecal pumps and 3 medical pump vendor representatives (pages 67-72 of application). The applicant also provided letters from a physician member of Neurosurgical Associates in Nashville and a member of Comprehensive Pain Specialists in Hendersonville (see 9/11 and 9/19 letters in Additional Information to Supplemental 4). Although the 2 physicians mention the need for the proposed service, no indication is given regarding the potential number of referrals.

Since the applicant is requesting a 95 county service area, it appears that this criterion has not been met.

b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant projects approximately 1,440 total visits in Year 1 for approximately 120 intrathecal pump patients increasing to 2,880 total visits in Year 2 for 240 patients (note: using estimates from existing intrathecal pump vendors, the applicant states that approximately 300 intrathecal pumps are currently in use in Tennessee). It expects to receive

referrals from physicians who initiate intrathecal implanted pump therapy such as neurosurgeons, other surgeons that may implant the pumps, and physicians with specialties in pain management or neurology. Clarification about the sources of referrals is addressed on page 22, Supplemental 2. The applicant notes that patients requiring skilled nursing services for assistance with infusion pump medication refills, titrations, and changes in medical condition would be candidates for referrals by physicians. However, as previously noted, the 2 physician referral letters did not specify the number of potential referrals.

It appears this criterion has been met.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided letters on pages 71 and 72 of the application from two individuals residing in Tennessee (Gainesboro and Lebanon) that state a home care option would be the best for them and their families. As noted, letters were provided by 2 physicians who practice in the Middle Tennessee area in Supplemental 4.

Since the applicant is requesting a 95-county service area, it appears that this criterion <u>has not been met</u>.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant describes the specialized and unique nature and scope of the proposed services in Section B, pages 11 and 12 and Section C, pages 20-24 of the application. ICD-9 codes and key CPT codes that illustrate same were submitted with Supplemental 3. Note: potential errors such as incorrect pump programming and incorrect medication dosage are discussed in more detail on pages 8 and 24 of Supplemental 1.

The applicant stated that Camellia Home Health (TN license # 0144) has the ability to provide skilled nursing services to intrathecal implanted pump patients in its 28 county East Tennessee service area. However, the applicant maintains that the agency's Director of Nursing states that Camellia has not yet provided intrathecal pump services to any of its Tennessee patients (page 2, Supplemental 4).

IPM's proposed specialty infusion services would be provided by trained nursing staff that must complete and pass a credentialed nurse training program. Based on all of the factors above, the applicant maintains that the provision of skilled nursing services for intrathecal pump patients is unique and does not appear to be provided by other existing home health agencies in Tennessee.

It appears this criterion <u>has been met.</u>

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.

The applicant projects an average gross charge of \$200 per skilled nursing visit based on 1,440 total projected visits in Year 1 and 2,880 total visits in Year 2 of the project. Note: the average charge excludes medications provided by the contracted pharmacy that will do its own billing for its services.

Per the response provided on page 19 of Supplemental 1, the applicant states that average cost is \$100.00 per visit. This appears to be relatively consistent with the \$105.24 cost per visit in Year 1 decreasing to approximately \$70.73 per visit in Year 2per the budgeted operating expenses in the Projected Data Chart of the application. Although there are no known agencies with similar services for comparison, the applicant notes that typical reimbursement by commercial plans ranges from \$150-\$250 per visit. The applicant also notes that Medicare does not cover its proposed skilled nursing services for home infusion services.

It appears this criterion has been met.

b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant expects to provide 1,440 total visits for approximately 120 patients per day in Year 1 increasing to 2,880 total visits for 240 patients in Year 2, based on 12 visits per intrathecal pump patient per year. As noted, it appears that there is an average cost of approximately \$105.24 per visit in Year 1 (note: this amount also equates to \$1,262.82 per patient in Year 1).

It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

Implanted Pump Management, LLC an existing, New Jersey Limited Liability Corporation formed in February 2012 and registered in Tennessee in October 2013, seeks approval to establish a home health organization and provide skilled nursing services limited to patients with surgically implanted intrathecal infusion therapy pumps. The applicant states that it also plans to provide services to implanted pump patients in other states in the near future, including Florida, Utah and New Jersey, subject to meeting appropriate licensure requirements. IPM's proposed nursing services will be provided to patients in their home under physician ordered plans of care. The proposed home health agency will be located in approximately 80 square feet of leased office space at 200 Prosperity Place, Suite 102 in Knoxville, Tennessee.

The applicant's nursing team will consist of 2-3 fulltime equivalent registered nurses in Year 1 that will serve approximately 120 patients in their homes statewide in all 95 Tennessee counties. IPM states that its nursing staff model is based on the following: 1) a staff ratio of one nurse to 40 patients, 2) a geographical coverage area within a 180-mile radius of the nurse's home address, and 3) capability of implementing any physician orders within 48 hours. The applicant will also provide a call center to expand contact with patients and physicians on a 24/7 basis. Additionally, patient physicians will have 24/7 secure access to their patient's clinical information using IPM's proprietary web portal. Melissa Hess, RN, the contact for the Certificate of Need application, will serve as the proposed agency's administrator.

As noted during review of the application by HSDA and the Tennessee Department of Health (TDH), the applicant has plans to contract with 2 specialty compounding pharmacies that are presently licensed by TDH to support the proposed intrathecal pump service in Tennessee. These include 1) Basic Home Infusion of Wayne, New Jersey, whose majority owner, Roy Putrino, is also the single member of the applicant LLC (*license* # 4656, *issued* 5/2009, *expires* 3/2016), and 2) Intrathecal Compounding Specialists (ICS) of Scott, Louisiana, which is not related by ownership to the applicant (*license* # 4485, *issued* 2/2008, *expires* 2/2016). Additional information about the Louisiana compounding pharmacy is provided on page 4 of supplemental 1 and attachment 4 of Supplemental 2. A draft contract between the applicant and ICS that identifies the responsibilities of

the parties is provided with the attachments to Supplemental 3. As indicated in the TDH summary, e-mail correspondence from the applicant addressed questions pertaining to the licensure status of both pharmacies, including status of corrective action in response to civil penalties, sanctions or judgments.

The payor types of home health patients to be served by the applicant will be commercial insurance that provide home care benefits or self-pay patients. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid. Although the applicant states that it has no plans to provide charity care, a small amount averaging approximately \$1,500 per year is budgeted in the Projected Data Chart for these patients.

The applicant maintains that its proposed in-home skilled nursing service activities required in connection with implanted pump infusion therapy patients focuses on serving as an "extension" to patient physicians to assist in facilitating the highest possible therapy outcomes. Key activities include patient/family education; medication administration for pump refills in accordance with physician orders; comprehensive nursing consisting of vital signs, determination of pain or spasticity level; complete head to toe assessment; and a telemetry reading of the pump in accordance with practice guidelines. These services will be provided by the applicant's registered nurse employees who must complete IPM's comprehensive nursing education program prior to being assigned a patient caseload. IPM's nursing staff roles and responsibilities are addressed on page 23 of the application. Additional clarification was provided on pages 1-2 of Supplemental 1, pages 3-7 of Supplemental 2 and pages 25-30 of the TDH questions in Exhibit 2 of Supplemental 3 (note: a copy of IPM's nursing training module was submitted with Supplemental 3).

The contracted compounding pharmacy is expected to be actively accredited and follow all state and federal regulations in regards to intrathecal pump medications and narcotics. The pharmacy will receive and process the physician orders then compound, package and ship the medication with a copy of the signed physician order to the applicant's assigned registered nurse (RN). The IPM staff nurse will then transport the medication to ensure temperature control and safety and will administer the medication to the patient in his/her home in accordance with signed physician orders. Types of infusion products to be administered include refills of intrathecal pump pain medications under physician orders for patients with cancer pain, multiple sclerosis or cerebral palsy. (Sources: page 22, Supplemental 1 and page 4, Supplemental 3)

Note to Agency Members: the above is a brief summary of the nature and scope of the proposed in-home skilled nursing service for infusion therapy patients. For more detailed descriptions about the nature and scope of services, including measures

taken to reduce the risks associated with these types of patients, please see the HSDA and TDH staff questions for Items 5.A - 5.L on pages 1-6 of Supplemental 1, Items 4.A-4.J on pages 3-7 of Supplemental 2 and Exhibit 1 and Exhibit 2 of Supplemental 3.

A description of patients with demonstrated needs for implanted pump infusion nursing services in the home that may otherwise be unavailable from other home health agencies is summarized as follows:

Implanted Intrathecal Pump Infusion Therapy - this highly specialized service is given to a very narrow and complex range of patients who have failed traditional therapy for severe or chronic pain and now rely on implanted drug delivery systems for their treatment. Types of patient conditions include pain secondary to cancer, multiple sclerosis, traumatic brain injury, head trauma, paralysis or stroke. Carefully selected by their physicians, these patients will have a specialized pump implanted in the intrathecal space surrounding the spinal cord during a surgical procedure in an inpatient or outpatient setting and their medication regimen started. Implanted pump infusion therapy may be appropriate for patients who have the care and resources available to manage potential risks such as infection, narcotic withdrawal, drug compounding errors and pump programming errors. Typical patient diagnoses include Chronic Pain Syndrome, Complex Regional Pain Syndrome, Multiple Sclerosis, Cerebral Palsy, Abnormal Involuntary Movement (Spasticity) and Traumatic Brain Injury. (For further detail regarding the ICD-9 codes that apply to these patients please see page 9, Supplemental 2).

Ownership

The applicant is a New Jersey limited liability corporation first formed in 2012 with one member, Mr. Roy Putrino, a licensed pharmacist located at 1401 Valley Road in Wayne, New Jersey. Mr. Putrino also has ownership interests in Basic Home Infusion Pharmacy (BHI), formerly Basic Home Care. BHI is one of the two pharmacies that the applicant intends to contract with for the proposed inhome intrathecal pump skilled nursing service.

- As described in more detail in the TDH summary, BHI holds an active non-resident Tennessee pharmacy license that was first issued by TDH in May 2009. BHI is also a licensed pharmacy in several other states, including Illinois, Colorado, Indiana, New Jersey and Indiana (note: please see questions to the applicant in the TDH summary pertaining to concerns and questions regarding BHI's prior history).
- The applicant expects to begin serving intrathecal pump patients in other states, including Florida, Utah and New Jersey, subject to state home health licensure requirements and related requirements or mandates.

- IPM holds a provisional home health license in Utah and is pending licensure in Florida.
- Per the applicant, it appears that IPM is exempt from home health licensure in New Jersey on the basis of providing one single service.
- An executive level organizational chart is provided on page 47 of the application.

Facility Information

- The parent office of the proposed project will be in approximately 80 square feet of leased space in an existing office building in downtown Knoxville at 200 Prosperity Place.
- The office will be used solely for administrative support purposes as a repository for home health service policies and procedures, personnel records and other required documentation.
- There is no construction, renovation or modification required to implement the proposed project.
- Per Item 4, page 10 of Supplemental 1, branch offices will not be used based on the specialized nature of the proposed service.

Project Need

- Lack of agencies that provide in-home skilled nursing care to intrathecal pump patients.
- Physicians requesting availability of in-home supportive nursing care model for their intrathecal pump patients.
- Need for specialized agency(s) that can serve as extension of physicians by providing nursing care to patients in their home and providing accurate and timely clinical information through secure means.
- Difficulty by patients to travel to physician for pump refills and office visits, especially patients with limited mobility or who are homebound.
- Need for accurate, reliable and timely information systems support to maintain patient medical record and facilitate communication with physicians through secure means. IPM's electronic medical record system and secure web portal for attending physicians appears to be innovative initiatives in addressing this need.
- As noted in this application and other similar projects for specialized infusion therapy services, traditional home health agencies do not typically provide in-home skilled nursing care for patients with surgically implanted intrathecal infusion pumps. Please note the comparison in the table below.

Comparison of Applicant to Other Types of Home Health Agencies

r	companion of applicant to other Types of Home Health Agencies			
Variable	Medicare Home Health Agency	Infusion Nursing Agency	Intrathecal Pump Service	
Average Visit Duration	One to Two Hours	Up to six hours	Up to two hours*	
Equipment	Generally not involved	Typically includes infusion equipment	Administration kit (syringes & other disposable items) Pump programmer	
Payor	80% Medicare and TennCare Patients	Private Insurance mainly	Commercial Insurance and Self-Pay	
Age	Approximately 68% Over Age 65+	Majority under Age 65	Not available	
Service Provided	44% is skilled nursing. Additional services may include therapy, home health aide, and medical social services.	100% specialized skilled nursing	100% specialized skilled nursing	
Patient Status	Homebound	Patient may or may not be homebound	May or may not be homebound	

*Note: the applicant states each patient may receive 12 visits per year. In addition, the patient should expect to visit his/her physician 4 times per year (page 25, Supplemental 1). Chart Sources include: CN1406-017A, CN1406-018A and CN1411-046 (pending)

• Note to Agency members: The attachment to the Department of Health Report indicated that based on 2013 data, 102,503 service area residents will need home health care in 2018; however 184,157 patients are projected to be served in 2018 resulting in a net excess of (81,654). Please note that this need is calculated for all home health patients, not just those needing home infusion services.

Service Area Demographics

- The proposed service includes all 95 Tennessee Counties.
- Per the TDH project summary, the total population of the 95 county statewide service area is expected to increase by approximately 3.7% from 6,588,698 residents in calendar year (CY) 2014 to 6,833,509 residents in CY 2018.
- The age 64 and younger population accounted for approximately 85.1% of the total population in CY2014. This age group is expected to increase by approximately 12.3% from 5,606,714 in 2014 to 5,731,096 in 2018.

- The 65 and older population accounted for approximately 14.9% of the total population in 2014. This age group is expected to increase by approximately 12.3% between 2014 and 2018.
- The latest 2014 percentage of the statewide population enrolled in the TennCare program is approximately 18.1%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

Service Area Historical Utilization

Using licensure and provider utilization records maintained by the Tennessee Department of Health, the applicant identified approximately 157 existing licensed home health agencies in Tennessee. The name of the agency, location of parent office, licensed counties and utilization for 2011 – 2013 is provided in the table on pages 4-13 of Supplemental 3. As a whole, the agencies served approximately 176,910 patients in 2011 decreasing by 0.5% to 175,924 patients in 2013.

Note to Agency members: The Joint Annual Report does not capture utilization data specific to implanted intrathecal pump therapy patients. There is not a known public database available that reports this type of data.

During review in 2012 of a previous Certificate of Need application for home infusion nursing (Coram Alternative Site Services), HSDA staff contacted the Tennessee Association of Home Care (TAHC) regarding home health providers and the Tennessee Hospital Association (THA) regarding hospital-based home care providers.

TAHC indicated the following:

- TAHC membership applications on file indicate that 224 home health offices (parents and branches) offer infusion therapy services.
- Standard home health policy is that first dose should be completed in the hospital setting.
- The majority of home health agencies partner with an infusion company for administration of the second dose in the home.
- The home health nurse continues to support the patient's needs with observations and reports to the physician. It is unrealistic to think that a home health provider could limit their care to only infusion therapy. Infusion may be the primary need but there are typically patients with multiple chronic illnesses and co-morbidities who need a holistic, multi-disciplinary approach to their health care
- The barriers to home infusion therapy are generally noted as staffing and adequate payment. This is a growing issue for all homecare providers as

- both governmental and commercial payors continue to look to provider payments to cut costs.
- Homebound status is only a Medicare issue. An infusion company would be held to the same standard if it were a Medicare-certified home health agency.

THA's response included that a "typical" home care provider does not provide infusion administration for:

- Patients requiring 6 hour therapies.
- Medicare patients who are not homebound which is a requirement that applies only to Medicare.
- Many non-Medicare patients who are not homebound are served
- Patients requiring first dose administration
- Patients requiring three doses daily

THA also advised that member home health agencies see patients in every county in the state and that there are pediatric programs often affiliated with pediatric hospitals such as Vanderbilt, Methodist LeBonheur, and East Tennessee Children's Hospital.

During review of this application and 2 Coram/CVS Certificate of Need projects for specialty infusion services (please see descriptions for CN1406-017A and CN1406-018A at the end of this summary), HSDA staff received confirmation by phone and by an email from a representative of TAHC that the TAHC information provided in 2012 was still accurate at the time the applicant's proposal was under review in 2014.

Applicant's Projected Utilization

- Per the applicant, implanted pump representatives estimate there were approximately 300 implanted pump patients in Tennessee during 2014.
- The applicant projects serving 120 patients in Year 1 increasing to 240 patients in Year 2
- The applicant is projecting 1,440 total visits in Year 1 increasing to approximately 2,880 visits in Year 2. The applicant bases the projected intrathecal pump patient visit schedule on approximately 12 skilled nursing visits per patient per year.
- IPM's projected patient caseload in Year 1 amounts to approximately 40% of the estimated 300 intrathecal pump patients in Tennessee in CY2014.
- Of the 121 projected implanted pump patients in Year 1, approximately 108 will be treated for diagnoses related to chronic pain, 11 for Cerebral Palsy and 2 for Multiple Sclerosis.

- The applicant estimates that approximately 2.2 million Tennesseans have chronic pain, 21,530 have Cerebral Palsy, and 7,169 have multiple sclerosis.
- A statewide profile by clinical classification by county is shown in the table on pages 28-31 of Supplemental 2.

Project Cost

Major costs of the \$13,038 total estimated project cost shown on page 32 of the application are as follows:

- Office Lease-\$8,738 or 67% of total cost
- Office supplies and pump programmer \$1,300
- Filing fee \$3,000

Applicant's Historical and Projected Data Chart

As noted, Implanted Pump Management LLC is a relatively new organization that has no financial record of operations involving the proposed home health services limited to infusion pump patients.

The projected financial performance of the project appears to be favorable as proceeds from operating revenues cover operational costs. Highlights from the Projected Data Chart on page 35 of the revised application are as follows:

- Projected gross operating revenue increases from \$288,000 on approximately 1,440 total implanted pump patient visits to \$576,000 on 2,880 visits in Year 2.
- The average gross charge is unchanged at \$200 per visit in Year 1 and Year 2.
- Salaries include \$125,000 for a full time Director of Nurses and a staff RN in Year 1 increasing to \$180,000 in Year 2, subject to expected increases in patient census.
- Net operating income is favorable at \$134,962 in Year 1 and \$369,562 in Year 2.
- Projected NOI calculates to approximately 46.9% of gross operating revenue in Year 1.
- Deductions from operating revenue for bad debt and charity are \$500 and \$1,000, respectively, in Year 1.

Charges

In Year One of the proposed project, the average charge per visit is as follows:

• The proposed average gross charge is \$200 per intrathecal pump patient visit in the first two years of the project.

- The average deduction for bad debt and charity averages approximately \$1.00 per patient visit.
- As noted, the applicant expects a reimbursement range of \$150-\$250 by most major commercial payors with a home nursing benefit. The applicant states that Medicare does not cover in-home nursing visits for intrathecal pump patients.

Medicare/TennCare Payor Mix

The applicant will not seek Medicare and Medicaid certification for the proposed home health agency limited to implanted infusion pump nursing services.

- Even if the applicant wanted to apply for Medicare/TennCare, it may not be eligible since the proposed limited scope of service would not be providing the full range of home health services prescribed by the Medicare Conditions of Participation.
- As noted, the contracted pharmacies participating in the project will be responsible for billing their fees related to dispensing implanted pump medications.
- The applicant's projected payor mix is 99% commercial insurance and 1% Self-Pay in Year 1.

Financing

The start-up costs for the project will be funded from cash reserves and appear minimal consisting primarily of a security deposit for leased office lease, supplies and the CON filing fee.

Review of IPM's unaudited financial statements and recent checking account statement confirmed the availability of approximately \$132,514 in checking/savings as of June 1, 2014 to fund the \$13,038 proposed project. Per the Balance Sheet, IPM reported total current assets of \$132,514 and total current liabilities of \$102,488 resulting in a current ratio of 1.27 to 1.0.

Note to Agency members: Current Ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant plans to use a 40 to 1 patient to nurse staffing ratio for the proposed agency with each nurse responsible for a geographic area within a 180 mile radius of his/her home of residence. IPM expects to hire approximately 2 full time equivalent (FTE) licensed nurses in Year 1. In addition, the applicant is

prepared to hire a third RN subject to increases in patient census. The home health agency's administrator will also have an assigned patient caseload.

Licensure/Accreditation

If approved, the applicant's proposed home health agency will be licensed by the Tennessee Department of Health.

- The applicant provided information regarding the licensing and accreditation of its existing or pending home health agencies in other sites.
- A copy of IPM's provisional Joint Commission Accreditation award for Home Care effective July 19, 2014 was provided with Supplemental 3.
- The applicant documented that the compounding pharmacies it expects to use to support the project are accredited. A copy of the Pharmacy Compounding Accreditation Board (PCAB) manual was provided with Supplemental 3 to document the standards related to this type of accreditation.
- As noted, the applicant also provided responses to questions and concerns addressed by TDH staff during its 60-day review period. These are shown in the TDH summary with attachments.

Corporate documentation, copies of the office lease, copies of related clinical literature, copies of the major ICD-9 and CPT codes that apply to implanted intrathecal pump patients, copies of policies and procedures, including Quality Assurance and Nurse Training Manual, and a copy of Humana Health Insurance provider manual are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **two** years.

Note to Agency members: Should the Agency choose to approve this application, Staff recommends the Agency limit any future expansion of services by requiring a new application to expand services beyond implanted intrathecal pump infusion services rather than a modification request through the General Counsel's Report. This could be accomplished with the following condition:

Home Health Agency services are limited to specialized skilled nursing services under physician ordered plans of care for patients with surgically implanted intrathecal pumps. The expansion of services beyond the home implanted pump infusion services described in the application will require the filing of a new certificate of need application.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent for other health care organizations in the service area proposing this type of service.

Pending Applications

Pentec Health, Inc., CN1411-046, has a pending application that will be heard under simultaneous review with CN1407-027 at the HSDA meeting on March 25, 2015 for the establishment of a home health agency to provide intrathecal pump services to patients across 92 counties of Tennessee. The estimated project cost is \$142,028.00.

The Home Option by Harden Healthcare, CN1501-001, has a pending application that will be heard under CONSENT CALENDAR REVIEW at the March 25, 2015 Agency meeting for the initiation of home health services in Blount, Campbell, Claiborne, Grainger, Monroe, Morgan, Roane and Scott Counties focusing on home health services to eligible individuals covered under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), United States Department of Labor. If approved, the applicant's sister agency, Gentiva Certified Healthcare Corporation, will de-license the same 8 counties. The Home Health Option by Harden is located at 800 Oak Ridge Turnpike, Suite A208, Oak Ridge (Anderson County), TN 37830 and is currently licensed in Anderson, Jefferson, Knox, Loudon, Sevier and Union Counties. The estimated project cost is \$38,000.00.

Denied Applications:

Home Care Agency of Middle Tennessee, CN1001-001D, was denied at the June 23, 2010 Agency meeting for the establishment of a home care organization focusing on a full range of home health services and skilled nursing psychiatric services for the elderly population in a four (4) county service area including Davidson, Rutherford, Sumner, and Williamson Counties from a parent office located at 5115 Maryland Way, Brentwood, (Williamson County), Tennessee. The estimated project cost was \$69,000.00. Reasons for Denial: There is not a need as there are other agencies in the proposed service area that are providing home health

services, including services to the mentally ill, and it is not economically feasible to have another agency. The project will not contribute to the orderly development of adequate and effective health care.

Rainbow Home Health, CN1111-045D, was denied at the February 22, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services, including skilled nursing, physical/occupational/speech therapies, and medical social services for individuals residing in Cheatham County from a home office located at 112 Frey Street in Ashland City (Cheatham County), Tennessee 37015. The estimated cost was \$262,600.00. Reasons for Denial: the prevailing reason for the vote leading to the denial of the project (4 ayes, 6 nays, 0 ties) was based on concerns with nature and scope of information provided by the applicant that did not support the need for the project, the economic feasibility or the orderly development of the project.

Rainbow Home Health, CN1203-013D, was denied at the June 27, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services from a home office located at 112 Frey Street, Ashland City (Cheatham County), Tennessee. The estimated project cost was \$27,950.00. Reasons for Denial: the application was denied by unanimous vote based on the following: there was no need due to services being adequately provided by existing licensed agencies in the service area; the project was not economically feasible due to the numbers not being justified or showing how the applicant could feasibly provide the service; and the project did not contribute to orderly development as it will impact the utilization and staffing of existing agencies in the service area.

Critical Nurse Staffing, CN1210-049D, was denied at the January 23, 2013 Agency meeting for the establishment of a home care organization located at 575 Oak Ridge Turnpike, Oak Ridge (Anderson County), Tennessee focusing on individuals eligible for benefits under either the Energy Employees Occupational Illness Compensation Program Act or the Federal Black Lung program that reside in Anderson, Campbell, Knox, Loudon, Monroe, Morgan, Roane, and Union Counties. The estimated project cost was \$155,937.00. Reasons for Denial: There was no real need - care was being adequately provided by other agencies in the proposed service area and adequate evidence did not support or prove that there was a need for the proposed agency.

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby, Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was \$177,800.00. Reasons for Denial: The need for the

proposed agency was not supported in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility - the project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.

Outstanding Certificates of Need:

Coram Alternate Site Services, Inc. d/b/a Coram Specialty Infusion Services **CN1406-018A** has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to the provision and administration of home infusion products and related ancillary services ancillary to its pharmacy services in a 25 county service area of West Tennessee, including the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, McNairy, Madison, Obion, Perry, Shelby, Stewart, Tipton, Wayne and Weakley Counties. The parent office will be located in its licensed home infusion pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee, 38134. The estimated project cost is \$98,000.00. Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the Tennessee Department of Health. The initial licensing inspection for the parent office in Memphis, TN has been scheduled for March 13, 2015. An Annual Project Report is due on or before July 1, 2015.

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, **CN1406-017A**, has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, and Washington Counties, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is \$95,200.00. Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the

Tennessee Department of Health. Notice of the inspection date is pending. An Annual Project Report is due on or before July 1, 2015.

Maxim Healthcare Services, CN1406-015A, has an outstanding Certificate of Need that will expire on October 1, 2016. The project was approved at the August 27, 2014 Agency meeting for the initiation of home health care services in a 5 county service area including Carter, Johnson, Sullivan, Unicoi, and Washington Counties focusing primarily on private duty hourly care to TennCare medically complex pediatric patients. Maxim Healthcare Services seeks an unrestricted home health agency license and will obtain Medicare certification to meet TennCare provider enrollment requirements. The estimated project cost is \$463,825.00. Project Status Update: per 2/27/15 e-mail from legal counsel for Maxim Health Care Services, the project was appealed but it appears that the parties have reached a settlement and the appeal may be dismissed in the near future. Confirmation of same will follow as soon as possible.

Hemophilia Preferred Care of Memphis, CN1202-002, has an outstanding certificate of need that will expire on August 1, 2015. The CON was approved at the June 27, 2012 agency meeting for the establishment of a home health agency and the initiation of home health services limited to patients suffering from hemophilia or similar blood disorders who are patients of the pharmacy operated by Hemophilia Preferred Care of Memphis. The estimated project cost is \$43,000. Project Status: The applicant requested and received approval at the June 25, 2014 Agency meeting for a one year extension from August 1, 2014 to August 1, 2015.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG 03/10/2015



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LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

of general circulation in [see attachment], Tennessee, on or before July 2nd (Year for one day. This is to provide official notice to the Health Services and Development Agency and all interested parties accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency and Develop	 es, ir
for one day. This is to provide official notice to the Health Services and Development Agency and all interested parties.	es, ir ency
This is to provide official notice to the Health Services and Development Agency and all interested parties accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Age	es, ir ency
This is to provide official notice to the Health Services and Development Agency and all interested parties accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Age	es, ir ency
Implanted Pump Management LLC	
(Name of Applicant) (Facility Type-Existing)	
owned by: Roy Putrino with an ownership type of Single Member LLC	
and to be managed by: Roy Putrino intends to file an application for a Certificate of Need	ed
for [PROJECT DESCRIPTION BEGINS HERE]:	
The establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The estimated project cost is \$8,100. The agency will utilize one office, locate 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be provided within all 95 Tennessee counties listed as follows: Anderson, Bedford, Benton, Bledsoe, Blount, Bradl Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, Dekalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdal Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putnam, Rhea, Roane Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, Wayne. Weakley, White, Williamson, Wilson, Wilson, Canno, Canno, Marion, Washington, Wayne, Weakley, White, Williamson, Wilson, Wilson, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, Wayne.	adley, dale, ane,
The anticipated date of filing the application is: July 7th . 20 14	
The contact person for this project is Melissa Hess Director of Nursing	
(Contact Name) (Title)	
who may be reached at: Implanted Pump Management 200 Prosperity Place #102	
(Company Name) (Address)	
Knoxville TN 37923 (201) 475-9635	
(City) (State) (Zip Code) (Area Code / Phone Number)	
7/1/14 info@ipmservices.org (Date) (E-mail Address)	

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243

The Tennessean Counties of Circulation: Robertson, Davidson, Dekalb, Williamson, Cheatham, Cannon, Bedford, Sumner, Hickman, Dickson, Smith, Rutherford, Montgomery, Moore, Lincoln, Marshall, Stewart, Houston, Trousdale, Humphreys, Warren, Maury, Wilson, Lawrence, Lewis, Putman, Jackson, Giles, Macon.



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(Facility Type-	Existing)
with an ownership type of Sir	igle Member LLC
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7th ₂₀ 14	
	Director of Nursing
	(Title)
	Place #102
	201) 475-9635 (Area Code / Phone Number)
	D@ipmservices.org (E-mail Address)
i t	with an ownership type of Sir intends to file an application intends to file an application intends to file an application of intrathecal pump services, The estimated project cost is \$8, ed within all 95 Tennessee counties listed as follows: Anders Cumberland, Davidson, Decatur, Dekalb, Dickson, Dyer, Fay Henderson, Henry, Hickman, Houston, Humphreys, Jackson Meigs, Monroe, Montgonery, Moore, Morgan, Obion, Overton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington 7th 2014 (Contact Name) ement 200 Prosperity Faxon (Address) 37923 (Zip Code)

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Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

The Commercial Appeal Counties of Circulation: Shelby, Crockett, Tipton, Dyer, Hardeman, Fayette, Haywood, Lauderdale, Gibson, McNairy, Chester, Henderson, Carroll, Madison.



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#### LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Par	is Post Intellig	encer	which is a newspaper
of general circulation in Carroll, Henry, Weakley, Bento	— uvame of Newsbar	per) —	ly 2nd , 2(14 (Year)
for one day.			(Today)
This is to provide official notice to the Health Service accordance with T.C.A. § 68-11-1601 et seq., and the	es and Develop e Rules of the l	ment Agency a Health Services	nd all interested parties, in and Development Agency,
Implanted Pump Management		LLC	
(Name of Applicant)		(Facility Type-I	Existing)
owned by: Roy Putrino	with an owners	ship type of Sin	gle Member LLC
and to be managed by: Roy Putrino	intends to file	an application t	or a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:			
The establishment of a home care organization and the initiation of home health services limited to int 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be provided Campbell, Cannon, Carroll, Carter, Chealtam, Chester, Claiborne, Clay, Cooke, Coffee, Crockett, Cu Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, He Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Mei Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, T	within all 95 Tennessee coun mberland, Davidson, Decatur nderson, Henry, Hickman, Ho gs, Monroe, Montgomery, Mo	ties listed as follows: Anderso, Dekalb, Dickson, Dyer, Faye uston, Humphreys, Jackson, ore, Morgan, Obion, Overton,	on, Bedford, Benton, Bledsoe, Blount, Bradley, lette, Fentress, Franklin, Gibson, Giles, Jefferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is: July 7	th	20 14	
The contact person for this project is Melissa Hess			Director of Nursing
(0	Contact Name)		(Title)
who may be reached at: Implanted Pump Manager	ment 20	0 Prosperity F	Place #102
(Company Name)	27000	(Address)	204) 475 0025
Knoxville TN (State)	37923 (Zip C		201) 475-9635 (Area Code / Phone Number)
1 Aux	7/1/14	linfo	@ipmservices.org
(Signature)	(Date)		(E-mail Address)
~ <del></del>			

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



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### LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Dai	ly News Journ		which is a newspaper
of general circulation in	(Name of Newspare), Tennessee,	on or before Ju	ly 2nd , 2(14 (Year)
for one day.			77
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This is to provide official notice to the Health Service accordance with T.C.A. § 68-11-1601 et seq., and the	es and Develop ne Rules of the I	ment Agency a Health Services	nd all interested parties, ir and Development Agency
Implanted Pump Management		LLC	
(Name of Applicant)	•	(Facility Type-E	
owned by: Roy Putrino	$\perp$ with an owners	ship type of Sin	gle Member LLC
and to be managed by: Roy Putrino			or a Certificate of Need
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The anticipated date of filing the application is: July 7	7th	. 20 14	
The contact person for this project is Melissa Hess			Director of Nursing
	Contact Name)		(Title)
who may be reached at: Implanted Pump Manage	ment 20	00 Prosperity F	Place #102
(Company Name)  Knoxville	37923		201) 475-9635
(City) (State)	(Zip (		(Area Code / Phone Number)
(Signature)	7/1/1 <del>/</del> (Date)	info	@ipmservices.org (E-mail Address)

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### LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

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of general circulation in Warren, Dekalb, Cannon, Van Burer	(Name of Newspar , Tennessee,	on or before	July 2nd , 2(14 (Year)
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This is to provide official notice to the Health Service accordance with T.C.A. § 68-11-1601 et seq., and the	s and Develop Rules of the h	ment Agency Health Service	and all interested parties, ir es and Development Agency
Implanted Pump Management		LLC	
(Name of Applicant)	1	(Facility Type	e-Existing)
owned by: Roy Putrino	with an owners	ship type of S	ingle Member LLC
and to be managed by: Roy Putrino	intends to file	an application	n for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:			
The establishment of a home care organization and the initiation of home health services limited to intr 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be provided v Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cun Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Hen Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meig Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Tr	vithin all 95 Tennessee count nberland, Davidson, Decatur, derson, Henry, Hickman, Ho s, Monroe, Montgomery, Mor	ties listed as follows: Ande , Dekalb, Dickson, Dyer, F uston, Humphreys, Jackst ore, Morgan, Objon, Overl	erson, Bedford, Benton, Bledsoe, Blount, Bradley, ayette, Fentress, Franklin, Gibson, Giles, on, Jefferson, Johnson, Knox, Lake, Lauderdale, ton, Perry, Pickett, Polk, Putnam, Rhea, Roane.
The anticipated date of filing the application is: July 7	:h	. 20 14	
The contact person for this project is Melissa Hess			Director of Nursing
(C	ontact Name)		(Title)
who may be reached at: Implanted Pump Managen (Company Name)	nent 20	0 Prosperity (Address)	Place #102
Knoxville TN	37923		(201) 475-9635
(City) (State)	(Zip C	ode)	(Area Code / Phone Number)
(Signature)	7/1/1 <del>4</del> (Date)	jin	fo@ipmservices.org (E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



The Publication of Intent is to be published in the	Buffalo River Rev	iew	which is a newspaper
of general circulation in Hickman, Perry, Wayne	(Name of Newshar	on or before Ju	ly 2nd , 2d14 (Month / day)
for one day.			Annuel troops and the second s
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This is to provide official notice to the Health Seraccordance with T.C.A. § 68-11-1601 et seq., and			
Implanted Pump Management		LLC	
(Name of Applicant)		(Facility Type-E	
owned by: Roy Putrino	with an owners	ship type of Sin	gle Member LLC
and to be managed by: Roy Putrino	intends to file	an application t	or a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:			
The establishment of a home care organization and the initiation of home health services limite 200 Prosperily Place #102, Knoxville, TN 37923, to service the entire state, Services will be pr Campbell, Cannon, Carroll, Carter. Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crock Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywo Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Mau Robertson, Rutherford, Scott, Sequalchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, T	rovided within all 95 Tennessee coun kett, Cumberland, Davidson, Decatur ood, Henderson, Henry, Hickman, Ho ury, Meigs, Monroe, Montgomery, Mo	ties listed as follows: Anderso , Dekalb, Dickson, Dyer, Faye suston, Humphreys, Jackson, ore, Morgan, Obion, Overton	n, Bedford, Benton, Bledsoe, Blount, Bradley, ltte, Fentress, Franklin, Gibson, Giles, Jefferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is: Ju	ly 7th	. 20 14	
The contact person for this project is Melissa Hes	SS		Director of Nursing
	(Contact Name)		(Title)
who may be reached at: Implanted Pump Mana	agement   20	0 Prosperity F	Place #102
(Company Name)		(Address)	
Knoxville TN	37923	(2	201) 475-9635
(City) (State)	(Zip C	Code)	(Area Code / Phone Number)
(Signature)	7/1/1 ⁴ (Date)	info	@ipmservices.org (E-mail Address)

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Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243



The Publication of Intent is to be published in the	Knoxville				which is a new	spaper
of general circulation in [see attachment]	(Nan , Te	ne of Newspa nnessee,	on or before	July	/ 2nd (Month / day)	2(14 (Year)
for one day.					(	N. L. STATE
~ <del>~</del>						
This is to provide official notice to the Health Se accordance with T.C.A. § 68-11-1601 et seq., and						
Implanted Pump Management			LLC			
(Name of Applicant)		-	(Facility T	/ре-Ех	isting)	
owned by: Roy Putrino	with	an owne	rship type of	Sing	le Member LLC	,
and to be managed by: Roy Putrino	inte	nds to file	e an applicati	on fo	r a Certificate o	f Need
for [PROJECT DESCRIPTION BEGINS HERE]:						
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who may be reached at: Implanted Pump Man	agement	2	00 Prosperi	-	ace #102	
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Knoxville		37923		_	01) 475-9635	
(City) (State	)	(Zip	Code)	()	Area Code / Phone Nu	imber)
(Signature)	<b>-</b>	7/1/14 (Date)		info(	Dipmservices. (E-mail Address)	org

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The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

The Knoxville News Sentinel Counties of Circulation: Grainger, Knox, Sevier, Union, Blount, Jefferson, Cumberland, Scott, Campbell, Claiborne, Anderson, Morgan, Roane, Loudon, Monroe, McMinn, Cocke.



The Publication of Intent is to be published	in the Murf	reesboro Dai		which is a newspaper
of general circulation in Rutherford, Bedford, Williams (County)	on, Wilson, Cannon	(Name of Newspa , <b>Tennessee</b> ,	on or before	July 2nd , 2(14 (Month / day) (Year)
for one day.				
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This is to provide official notice to the He accordance with T.C.A. § 68-11-1601 et s				
Implanted Pump Management			LLC	
(Name of Applicant)			(Facility Ty	
owned by: Roy Putrino		with an owner	ship type of	Single Member LLC
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The establishment of a home care organization and the initiation of home health 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Ser Campbell, Cannon, Carroll, Carter. Cheatham, Chester, Claiborne, Clay, Cocke Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sulliv	vices will be provided wi , Coffee, Crockett, Cum awkins, Haywood, Henc Marshall, Maury, Meigs	thin all 95 Tennessee cour berland, Davidson, Decatu lerson, Henry, Hickman, He , Monroe, Montgomery, Mo	nlies listed as follows: An r, Dekalb, Dickson, Dyer, ouston, Humphreys, Jack oore, Morgan, Obion, Ove	derson, Bedford, Benton, Bledsoe, Blount, Bradley, Fayette, Fentress, Franklin, Gibson, Giles, son, Jefferson, Johnson, Knox, Lake, Lauderdale, arton, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application	July 7t	h	20 14	
The contact person for this project is Melis	ssa Hess			Director of Nursing
	(Co	ntact Name)		(Title)
who may be reached at: Implanted Pum	p Managem	ent 20	00 Prosperit	y Place #102
(Company Na			(Address)	
Knoxville	TN	37923		(201) 475-9635
(City)	(State)	(Zip (	Code)	(Area Code / Phone Number)
Milando		7/1/14		nfo@ipmservices.org
(Signature)		(Date)		(E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

~________________

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



The Publication of Intent is to be published in the	Johnson C			which is a newspaper
of general circulation in Washington, Sullivan, Carter, Greene, Unicoi, Ha	(Name ( awkins, Johnson , Tenr	of Newspape nessee, c	on or before	July 2nd , 2(14 (Year)
for one day.				(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
~===~====	: = <del></del> = =			
This is to provide official notice to the Health accordance with T.C.A. § 68-11-1601 et seq.,	Services and I and the Rules	Developn of the H	nent Agency lealth Service	and all interested parties, in es and Development Agency
Implanted Pump Management			LLC	
(Name of Applicant)		5	(Facility Typ	
owned by: Roy Putrino	with ar	owners	hip type of <mark></mark> S	ingle Member LLC
and to be managed by: Roy Putrino				n for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:				
The establishment of a home care organization and the initiation of home health services 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state Services will Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Hawrence, Lewis, Lincoln, Loudon, McWinn, McNairy, Macon, Madison, Marion, Marshall, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumr	be provided within all 95 Te Crockett, Cumberland, Dav Haywood, Henderson, Henn H, Maury, Meigs, Monroe, Me	ennessee countie idson, Decatur, I y, Hickman, Hou ontgomery, Moo	es listed as follows: And Dekalb, Dickson, Dyer, I Iston, Humphreys, Jacks re, Morgan, Obion, Ovel	erson, Bedford, Benton, Bledsoe, Blount, Bradley, -ayette, Fentress, Franklin, Gibson, Giles, ion, Jefferson, Johnson, Knox, Lake, Lauderdale, ton, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is:	July 7th		20 14	
The contact person for this project is Melissa H	Hess			Director of Nursing
	(Contact Nan	ne)		(Title)
who may be reached at: Implanted Pump Ma	anagement	200	O Prosperity (Address)	Place #102
Knoxville TN		37923	(Address)	(201) 475-9635
	tate)	(Zip Co	ode)	(Area Code / Phone Number)
(Signature)	7/	1/14 (Date)	in	fo@ipmservices.org (E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243



The Publication of Intent is to be published in the			which is a newspaper
of general circulation in Washington, Sullivan, Hawkins, Carter, Gree (County)	(Name of Newspa , Tennessee,	on or before Jul	y 2nd , 2d14 (Year)
for one day.			(roar)
~			
This is to provide official notice to the Health Saccordance with T.C.A. § 68-11-1601 et seq., a	Services and Develop and the Rules of the	ment Agency ar Health Services	nd all interested parties, in and Development Agency,
Implanted Pump Management		LLC	
(Name of Applicant)		(Facility Type-E	xisting)
owned by: Roy Putrino	with an owner	ship type of Sing	gle Member LLC
and to be managed by: Roy Putrino			or a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:			
200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state, Services will be Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, C Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Ha Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumne	ockett, Cumberland, Davidson, Decatu ywood, Henderson, Henry, Hickman, Ho Maury, Meigs, Monroe, Montgomery, Mo	r, Dekalb, Dickson, Dyer, Fayet buston, Humphreys, Jackson, J bore, Morgan, Obion, Overton, I	tte, Fentress, Franklin, Gibson, Giles, Jefferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is:	uly 7th	20 14	
The contact person for this project is Melissa H			Director of Nursing
·	(Contact Name)		(Title)
who may be reached at: Implanted Pump Mai	nagement 20	00 Prosperity P	lace #102
(Company Name)		(Address)	
Knoxville	37923		01) 475-9635
(City) (Sta	(Zip (	Code) (	Area Code / Phone Number)
Allas	711/14	info	@inmana inna aua
(Signature)	(Date)	Tillo	@ipmservices.org

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



The Publication of Intent is to be published in the _	Jackson :	Sun			which is a newspaper
of general circulation in Crockett, Madison, Gibson, Decatur,			on or before	Jul	/ 2nd , 2d 14 (Year)
for one day.					N SA N
~			==		
This is to provide official notice to the Health Se accordance with T.C.A. § 68-11-1601 et seq., ar					
Implanted Pump Management			LLC		
(Name of Applicant)		=	(Facility Ty		
owned by: Roy Putrino	with	an owner	ship type of	Sing	le Member LLC
and to be managed by: Roy Putrino					or a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:					
The establishment of a home care organization and the initiation of home health services limit 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be p Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crot Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Hayw, Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Ma Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner,	provided within all 95 ckett, Cumberland, E vood, Henderson, He aury, Meigs, Monroe,	Tennessee coun Pavidson, Decatur enry, Hickman, Ho Montgomery, Mo	aties listed as follows: An r. Dekalb, Dickson, Dyer ouston, Humphreys, Jac bore, Morgan, Obion, Ov	derson , Fayeti kson, J erton, f	, Bedford, Benton, Bledsoe, Blount, Bradley, Le, Fentress, Franklin, Gibson, Giles, efferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is: Ju	ıly 7th		_{. 20} 14		
The contact person for this project is Melissa He	SS			7 [	Director of Nursing
	(Contact N			-11	(Title)
who may be reached at: Implanted Pump Man	agement	20	00 Prosperit		ace #102
Knoxville (Company Name)		37923	(Address)	_	01) 475-9635
Knoxville TN (State	)	(Zip (	Code)		Area Code / Phone Number)
15 Charlo	7	11/14		nfo	@ipmservices.org
(Signature)		(Date)			(E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



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### LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the	Greenville Sun		which is a newspaper
of general circulation in Greene, Washington, Hav		on or before Ju	ly 2nd , 2(14 (Year)
for one day.			3. 22 8. 750
This is to provide official notice to the Health Se accordance with T.C.A. § 68-11-1601 et seq., an	rvices and Develop of the Rules of the I	ment Agency a Health Services	nd all interested parties, ir and Development Agency
Implanted Pump Management		LLC	
(Name of Applicant)		(Facility Type-I	
owned by: Roy Putrino	with an owners	ship type of Sin	gle Member LLC
and to be managed by: Roy Putrino	intends to file	an application	for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:			
The establishment of a home care organization and the initiation of home health services limit 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be p Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Croc Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Hayw Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Marobertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner,	provided within all 95 Tennessee coun ckett, Cumberland, Davidson, Decatur cketd, Henderson, Henry, Hickman, Ho ury, Mejas, Monroe, Montgomery, Mo	ties listed as follows: Anderso ; Dekalb, Dickson, Dyer, Fayo buston, Humphreys, Jackson, hore, Morgan, Obion, Overton	on, Bedford, Benton, Bledsoe, Blount, Bradley, ette, Fentress, Franklin, Gibson, Giles, Jefferson, Johnson, Knox, Lake, Lauderdale, , Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is: Ju	ıly 7th	. 20 14	
The contact person for this project is Melissa He	SS		Director of Nursing
	(Contact Name)	15	(Title)
who may be reached at: Implanted Pump Mana	agement 20	00 Prosperity F	Place #102
(Company Name)		(Address)	
Knoxville	37923	(2	201) 475-9635
(City) (State)	(Zip C	Code)	(Area Code / Phone Number)
Mass	7/1/14	info	@ipmservices.org
(Signature)	(Date)		(E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



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### LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in	the Clar	ksville The L		Chronicle	which is a newspaper
of general circulation in Montgomery (County)		Name of Newsp , Tennessee	oaper) e, on o	r before J	uly 2nd , 2(14
for one day.					Control of the contro
~			_ = -		
This is to provide official notice to the Healt accordance with T.C.A. § 68-11-1601 et sec	th Service $q_{\cdot,i}$ and the	s and Develo Rules of the	opmen Heal	t Agency th Service	and all interested parties, ir s and Development Agency
Implanted Pump Management			LL	_C	
(Name of Applicant)				(Facility Type	
owned by: Roy Putrino		with an owne	ership	type of S	ingle Member LLC
and to be managed by: Roy Putrino		intends to fi	le an a	application	for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:					
The establishment of a home care organization and the initiation of home health sen 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Cot Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkl Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion. Mar Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan.	s will be provided v fee, Crockett, Cun ns, Haywood, Her shall, Maury, Meio	vithin all 95 Tennessee on berland, Davidson, Deca derson, Henry, Hickman, s. Monroe, Montgomery,	ounties liste atur, Dekalt , Houston, I Moore, Mo	ed as follows: Ande o, Dickson, Dyer, F Humphreys, Jackson Ingan, Obion, Oven	rson, Bedford, Benton, Bledsoe, Blount, Bradley, ayette, Fentress, Franklin, Gibson, Giles, on, Jefferson, Johnson, Knox, Lake, Lauderdale, on, Perry, Pickett, Polk, Pulnam, Rhea, Roane,
The anticipated date of filing the application is	July 7	th	. 20	14	
The contact person for this project is Melissa	a Hess				Director of Nursing
The contact percent of the project of	(C	ontact Name)			(Title)
who may be reached at: Implanted Pump Management 200 Prosperity Place #102					
(Company Name	)			(Address)	
Knoxville		37923			(201) 475-9635
(City)	(State)	(Zi	p Code)		(Area Code / Phone Number)
Mins		7/1/14		in	fo@ipmservices.org
(Signature)		(Date)			(E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243



The Publication of Intent is to be published in the	Coc	keville Herald	d Citizen	which is a newspaper	
of general circulation in Putnam, Jackson, Overton, White, Clay, Pi			on or before	July 2nd , 2(14 (Month / day) (Year)	
for one day.					
~	= =		==		
This is to provide official notice to the Health accordance with T.C.A. § 68-11-1601 et seq.,	Service and the	es and Develop e Rules of the	oment Agency Health Service	y and all interested parties, in ses and Development Agency,	
Implanted Pump Management			LLC		
(Name of Applicant)			4	pe-Existing)	
owned by: Roy Putrino		_with an owne	rship type of	Single Member LLC	
and to be managed by: Roy Putrino		7		on for a Certificate of Need	
for [PROJECT DESCRIPTION BEGINS HERE]:					
The establishment of a home care organization and the initiation of home health services 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claibome, Clay, Cocke, Offee, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshal Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sum	I be provided Crockett, Cui Haywood, Hei Il Maury Mei	within all 95 Tennessee cou nberland, Davidson, Decat nderson, Henry, Hickman, I as Monroe Montgomery, N	ınties listed as follows: Ar ur, Dekalb, Dickson, Dyer Houston, Humphreys, Jac Noore, Morgan, Obion, Ov	iderson, Bedford, Benton, Bledsoe, Blount, Bradley, Fayette, Fentress, Franklin, Gibson, Giles, kson, Jefferson, Johnson, Knox, Lake, Lauderdale, rerton. Perry. Pickett, Polk, Putnam. Rhea, Roane,	
The anticipated date of filing the application is:	July 7	th	. 20 14		
The contact person for this project is Melissa	Hess			Director of Nursing	
The contact person for this project is memorial	(C	ontact Name)		(Title)	
who may be reached at: Implanted Pump Ma	anager	ment 2	00 Prosperit	y Place #102	
(Company Name) (Address)					
Knoxville		37923		(201) 475-9635	
(City) (S	itate)	(Zip	Code)	(Area Code / Phone Number)	
1/1/1000		7/1/14		nfo@ipmservices.org	
(Signature)	= = =-	(Date)		/	

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243



The Publication of Intent is to be published in the Dyersburg State Gazette which is a new state of the publication of Intent is to be published in the Dyersburg State Gazette	wspaper				
of general circulation in Dyer, Crockett, Lauderdale, Lake, Obion, Tennessee, on or before July 2nd  (County)  (Month / day)	, 2(14 (Year)				
for one day.					
vactureturetureturetureturetureturetureture					
This is to provide official notice to the Health Services and Development Agency and all interests accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development	ed parties, in nent Agency				
Implanted Pump Management LLC					
(Name of Applicant) (Facility Type-Existing)	32				
owned by: Roy Putrino with an ownership type of Single Member L	LC				
and to be managed by: Roy Putrino intends to file an application for a Certificate					
for [PROJECT DESCRIPTION BEGINS HERE]:					
The establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The estimated project cost is \$8,100. The agency will utilize 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be provided within all 95 Tennessee counties listed as follows: Anderson, Bedford, Benton, Bleds Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, Dekalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gil Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lawrence, Lewis, Lincoin, Loudon, McMinn, McMinn, McMarion, Marion, Marion, Marion, Marion, More, Montgomery, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putta Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Washington, Wayne, Weakley, White, Van Buren, Washington, Wayne, Washington, Wayne, Weakley, White, Van Buren, Washington, Wayne, Washin	e, Blount, Bradley, son, Giles, Lake, Lauderdale, m, Rhea, Roane,				
The anticipated date of filing the application is: July 7th July 7th					
The contact person for this project is Melissa Hess  Director of N	ursing				
(Contact Name) (Title)					
who may be reached at: Implanted Pump Management 200 Prosperity Place #102					
(Company Name) (Address)					
Knoxville TN 37923 (201) 475-963	5				
(City) (State) (Zip Code) (Area Code / Phone	Number)				
7/1/14 info@ipmservice	,				

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243



The rabileation of intent is to be published in the	ga Times Free Press which is a newspaper
of general circulation in [see attachment], Tenn	of Newspaper) nessee, on or before July 2nd (Month / day) (Year)
for one day.	(world rody) (rod)
~******************	weerveerveerve
This is to provide official notice to the Health Services and I accordance with T.C.A. § 68-11-1601 et seq., and the Rules	Development Agency and all interested parties, in of the Health Services and Development Agency
Implanted Pump Management	LLC
(Name of Applicant)	(Facility Type-Existing)
owned by: Roy Putrino with an	ownership type of Single Member LLC
D - v D - t - i	s to file an application for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:	
The establishment of a home care organization and the initiation of home health services limited to intrathecal pump 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be provided within all 95 Te Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davi Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Mo Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unico	Innessee counties listed as follows: Anderson, Bedford, Benton, Bledsoe, Blount, Bradley, Idson, Decatur, Dekalb. Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, andcomerv, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putnam Rhea, Roane
The anticipated date of filing the application is: July 7th	. 20 14
The contact person for this project is Melissa Hess	Director of Nursing
(Contact Nam	
who may be reached at: Implanted Pump Management	200 Prosperity Place #102
(Company Name)	(Address)
	37923 (201) 475-9635
(City) (State)	(Zip Code) (Area Code / Phone Number)
11/200 111	
(Signature)	info@ipmservices.org

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

> **Health Services and Development Agency** The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243

The Chattanooga Times Free Press Counties of Circulation: Moore, Franklin, Hamilton, Meigs, Bradley, Rhea, Cumberland, Roane, Coffee, Grundy, Marion, Sequatchie, Van Buren, Bledsoe, McMinn, Polk.



The Publication of Intent is to be published in the _	Rogersville Revie		which is a newspaper		
of general circulation in Hawkins, Sullivan, Greene, Hancock, Grainger (County)	(Name of Newspar , Tennessee,	on or before Jul	y 2nd , 2(14 (Month / day) (Year)		
for one day.			The second of th		
~					
This is to provide official notice to the Health Se accordance with T.C.A. § 68-11-1601 et seq., ar	ervices and Develop nd the Rules of the I	ment Agency ar Health Services	nd all interested parties, i and Development Agency		
Implanted Pump Management		LLC			
(Name of Applicant)		(Facility Type-E	ixisting)		
owned by: Roy Putrino	with an owner	ship type of Sing	gle Member LLC		
and to be managed by: Roy Putrino			or a Certificate of Need		
for [PROJECT DESCRIPTION BEGINS HERE]:					
The establishment of a home care organization and the initiation of home health services limi 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be p Campbell, Cannon, Carroli, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Cro Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawklins, Hayw Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Ma Robertson, Rutherford, Scott, Sequatchie, Sevier, Sheiby, Smith, Stewart, Sullivan, Sumner,	provided within all 95 Tennessee cour ckett, Cumberland, Davidson, Decatur vood, Henderson, Henry, Hickman, Ho Bury, Meigs, Monroe, Montgomery, Mc	ties listed as follows: Anderso ; Dekalb, Dickson, Dyer, Faye puston, Humphreys, Jackson, pore Morgan, Objon, Overton,	n, Bedford, Benton, Bledsoe, Blount, Bradley, Itte, Fentress, Franklin, Gibson, Giles, Jefferson, Johnson, Knox, Lake, Lauderdale, Perry, Pickett, Polk, Putnam, Rhea, Roane.		
The anticipated date of filing the application is:	uly 7th	. 20 14			
The contact person for this project is Melissa He	ess		Director of Nursing		
(Contact Name) (Title)					
who may be reached at: Implanted Pump Man	agement 20	00 Prosperity F	Place #102		
(Company Name)		(Address)			
Knoxville	37923	(2	201) 475-9635		
(City) (State	(Zip (	Code)	(Area Code / Phone Number)		
(Signature)	7/1/14 (Date)	info	@ipmservices.org (E-mail Address)		

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243



The Publication of Intent is to be published in the Bri	istol Herald Cοι		which is a newspaper
of general circulation in Carter, Sullivan, Washington, Greene, Hawkins, John (County)	(Name of Newspar , Tennessee,	on or before J	uly 2nd , 2d14 (Year)
for one day.			With the second second
~			~~==~~=
This is to provide official notice to the Health Service accordance with T.C.A. § 68-11-1601 et seq., and the seq., and the seq.	ces and Develop he Rules of the l	ment Agency a Health Services	and all interested parties, in s and Development Agency,
Implanted Pump Management		LLC	
(Name of Applicant)		(Facility Type	-Existing)
owned by: Roy Putrino	with an owners	ship type of Si	ngle Member LLC
and to be managed by: Roy Putrino	intends to file	an application	for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]:			
The establishment of a home care organization and the initiation of home health services limited to 200 Prosperity Place #102, Knoxville, TN 37923, to service the entire state. Services will be provide Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, CGrainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Flawrence, Lewis, Lincotn, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, M Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton	ed within all 95 Tennessee coun Cumberland, Davidson, Decatur Henderson, Henry, Hickman, Ho Jeigs, Monroe, Montgomery, Mo	ties listed as follows: Ander Dekalb, Dickson, Dyer, Fa uston, Humphreys, Jackso ore, Morgan, Obion, Overto Buren, Warren, Washingto	son, Bedford, Benton, Bledsoe, Blount, Bradley, lyette, Fentress, Franklin, Gibson, Giles, n, Jefferson, Johnson, Knox, Lake, Lauderdale, n, Perry, Pickett, Polk, Putnam, Rhea, Roane,
The anticipated date of filing the application is: July	7th	_{. 20} 14	
The contact person for this project is Melissa Hess			Director of Nursing
	(Contact Name)		(Title)
who may be reached at: Implanted Pump Manage (Company Name)	ement 20	0 Prosperity (Address)	Place #102
Knoxville TN	37923		201) 475-9635
(City) (State)	(Zip C		(Area Code / Phone Number)
(Signature)	7/1/14 (Date)	inf	o@ipmservices.org (E-mail Address)

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency The Frost Building, Third Floor 161 Rosa L. Parks Boulevard Nashville, Tennessee 37243



December 2, 2014

Ms. Melanie Hill, Executive Director Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

RE: Implanted Pump Management, LLC, CN1407-027 OPPOSITION LETTER

Dear Ms. Hill:

We are aware of the intent of Implanted Pump Management, LLC to establish a new Home Health Care service organization limited to intrathecal home infusion services and to provide services to all 95 counties in the State of Tennessee from one office in Knoxville. NHC has serious concerns regarding numerous aspects of the referenced CON application including but not limited to whether there is a demonstrated need in the State of Tennessee for such services, whether or not the proposed service delivery model is even legal in the State, that approval of said application would duplicate existing similar services already approved by HSDA, and that the project would adversely impact the existing home health care delivery system. Therefore, I am writing this letter in opposition to the referenced project pursuant to T.C.A., Section 68-11-1609(g) (1).

In recent months, there has been an alarming trend of applicants requesting Home Care CON's to service all 95 counties in Tennessee with limited staff, single office locations and with a single specialty focus that will do nothing more than further fragment the health care delivery system in our State. In addition, these recent CON's appear to fall outside the established criteria for the home care service. Consequently, it would seem appropriate that until further study is conducted on what criteria should actually be used to evaluate said CON's, a moratorium should be imposed on CON's of this type prohibiting their acceptance and review before the agency

In summary, I am opposed to this CON and ask that it not be approved. There are many unanswered questions regarding this application and more than adequate existing providers delivering high quality home health services to populations of all race and payment source. If you need any additional information please do not hesitate to call me.

Sincerely,

NHC/OP, L.P. d/b/a NHC HomeCare

Lisa Reed, RN

Vice President/HomeCare

Cc: Ms. Melissa Hess, DON

200 Prosperity Place, #102

Knoxville, TN 37923



Waller Lansden Dortch & Davis, LLP 511 Union Street, Suite 2700 P.O. Box 198966 Nashville, TN 37219-8966

Kim Harvey Looney 615.850,8722 direct kim.looney@wallerlaw.com 615,244,6380 main 615,244,6804 fax wallerlaw.com

June 8, 2015

#### VIA HAND DELIVERY

Melanie Hill Health Services and Development Agency Andrew Jackson Building 9th Floor 502 Deaderick Street Nashville, TN

Re: Implanted Pump Management CN1407-027

Dear Melanie:

This is to provide official notice that our client, Pentec Health, Inc., wishes to oppose the application of Implanted Pump Management CN1407-027 for the establishment of a home care organization and the initiation of specialized home health services limited to intrathecal pump services. Pentec Health, Inc. has filed an application for the establishment of a home care organization and the initiation of specialized home health services related to home fusion for patients with implanted intrathecal infusion pumps and patients receiving immunoglobulin-G replacement therapy. This application will be heard, along with the Implanted Pump Management application, at the June meeting. To the extent only one application is approved, Pentec feels it is the more qualified applicant.

If you have any questions, please give me a call at 850-8722 or by email at kim.looney@wallerlaw.com.

Sincerely,

Kim Harvey Looney

KHL:lag

cc: Robert A. Provonche (Pentec Health, Inc.)
Karen McHenry (Pentec Health, Inc.)

Steven Behrens - (Pentec Health, Inc.) Richard Leigh, Esq.(Saul & Ewing)

Rachel C. Nelley, Esq.

# CERTIFICATE OF NEED REVIEWED BY THE DEPARTMENT OF HEALTH DIVISION OF POLICY, PLANNING AND ASSESSMENT

615-741-1954

DATE:

November 28, 2014

**APPLICANT:** 

Implanted Pump Management, LLC

200 Prosperity Place, #102 Knoxville, Tennessee 37923

**CON #:** 

CN1407-027

CONTACT PERSON:

Mellissa Hess, Director of Nursing

200 Prosperity Place

Knoxville, Tennessee 37923

COST:

\$13,038

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

#### **SUMMARY:**

The applicant, Implanted Pump Management, (IPM) LLC, located at 200 Prosperity Place, #102, Knoxville (Knox County), Tennessee, seeks Certificate of Need (CON) approval for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The service includes refills, titrations, 24-hour on call services, and advanced information technology that simulates telemedicine for participating providers. The applicant will lease 325 square feet of office space in Knoxville. The applicant's declared service area includes all 95 Tennessee counties.

Implanted Pump Management, LLC, is a New Jersey LLC formed in 2012 and registered to do business in Tennessee since October 2013. IPM is a single owner LLC owned by Roy Putrino, a licensed New Jersey pharmacist. Mr. Putrino is a 70% owner of Basic Home Infusion Pharmacy (BHI) that previously operated as Basic Home Care. BHI will be one of two compounding pharmacy contractors involved in this project. IPM is applying for a Home Health license in Florida and has been granted a provisional Home Health license (#2014-HHAUT000641) in Utah. New Jersey has exempted IPM from requiring home health licensure due to their provision of one skilled service. The applicant reports they will soon begin serving patients in Florida, New Jersey, and Utah. Currently, IPM is not serving any patients in any States.

The total estimated project cost is \$13,038 and will be funded through cash reserves.

#### **GENERAL CRITERIA FOR CERTIFICATE OF NEED**

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

#### **NEED:**

The applicant intends to serve patients in all 95 of Tennessee's counties. See Attachment 1 for population projections.

Implanted Pump Management, Inc. is a relatively new company formed in 2012. The applicant reports they are in the process of receiving a license, have a provisional license, or are exempt from needing a license in Florida, Utah, and New Jersey, respectively. However, to this point, the

applicant has not provided intrathecal pump services to any patients in any of these States.

Implanted Pump Management, Inc. proposes to provide intrathecal pump services to individuals who have one of two diagnoses: pain and/or intractable spasticity. These two diagnoses should provide a varied patient population that the applicant believes could benefit from home pump management.

The individuals with chronic pain could range from those individuals who are highly debilitated to those who have the ability to work fulltime.

Individuals who have intractable spasticity most generally suffer from diseases such as:

- Multiple sclerosis;
- Cerebral palsy;
- Traumatic brain injury;
- Spinal cord injuries; and
- Varied neurological disorders

IPM projects 120 patients in year one and 240 patients in year two of the project. The applicant estimates the percentage of the patients who will receive their services will be 90% pain management, 1% multiple sclerosis, and 9% cerebral palsy in both years, respectively.

Due to the nature of both these diagnoses, both physical and economic challenges can be encountered when a patient's only choice is to go to a medical doctor's office for this service.

The service includes refills, titrations, 24-hour on call services, and advanced information technology that simulates telemedicine for participating providers.

The applicant believes a need exists for their proposed several reasons. First, No Home Health Agency in Tennessee provides this specialized, technical service in the home; Second, Medtronics, a leading pump manufacturer, reports 300 patients residing individuals residing in Tennessee currently have intrathecal pumps; Third, Physician's requests for IMP to enter the State of Tennessee; and Fourth, requests from patients who would like to have access to this service in their homes.

The following concerns and questions were asked by Department of Health staff in order to ascertain the applicant's prior history serving patients needing intrathecal pump management services, the number of patients served, and any quality issues that might exist in other states. The applicant's replies follow the questions asked by staff.

10/13/2014 Mellissa Hess, Director of Nursing,

Please provide me further information regarding CN1407-027. Specifically I need detailed answers to the following questions.

- 1 The number of patients currently being seen by IPM in Florida and New Jersey. If no patients are being served, please explain. Have any services ever been performed by IPM since its inception in December 2012?
- 2) License numbers if applicable from the New Jersey and Florida Departments of Health.

- 3) All surveys performed by the respective health departments and plans of correction, sanctions, monetary penalties, or judgments against IPM if applicable.
- 4) Does Mr. Putrino own Health Care Infusion? If yes, do they perform pump management services? Does he own Basic Home Health Care? If yes, please provide surveys and plans of correction, sanctions, monetary penalties, or judgments against said companies.

Joe F. Culp, Health Planner III
Tennessee Department of Health
Division of Policy, Planning, and Assessment
Andrew Johnson Tower
710 James Robertson Parkway
Nashville, Tennessee 37243
615-741-0244

From: IPM [mailto:info@ipmservices.org]
Sent: Monday, October 13, 2014 12:36 PM

To: 'Joe F. Culp'

Subject: RE: Implanted Pump Management CN1407-027

Mr. Culp,

In response to your previous inquiries:

- 1) IPM is not currently servicing any patients. Within the next 6 weeks, IPM will begin servicing patients in Florida, New Jersey and Utah. This time frame is based on licensure requirements and state mandates.
- 2) The state of New Jersey has deemed IPM exempt from requiring home health agency licensure due to our provision of one single skilled service. IPM is still in the process of applying for licensure in the state of Florida. IPM has received a survey approved by The Joint Commission (TJC) for this licensure. We are waiting for the final license to be issued. IPM has been granted a provisional home health agency license in the state of Utah. The number of this license is as follows; 2014-HHAUT000641.
- 3) Please see attached preliminary survey performed by TJC. IPM has no other plans of correction, sanctions, monetary penalties, or judgments.
- 4) Mr. Putrino does not own, nor is he affiliated, with Health Care Infusion. Mr. Putrino is part owner of the Basic Home Infusion Pharmacy (BHI), which previously operated as Basic Home Health Care. Basic Home Infusion does provide intrathecal pump management services. Please see attached order from Indiana, order from Illinois, and stipulations from Colorado.

Please note attached TJC accreditation and pharmacy inspections regarding zero deficiencies as evidence of corrective action regarding issues in Illinois and Colorado. In reference to the attached final order received from the state of Indiana, BHI has successfully subcontracted with 3 licensed home health agencies within the state to provide intrathecal home care services.

Thank You,
Brynn Beekman
Administrative Assistant
Implanted Pump Management
T: (201) 475-9635
F: (201) 475-9630
info@IPMservices.org

10/17/2014 Ms. Hess: Thank you for your timely responses to my previous questions. I have several more now and perhaps more later as I delve through this lengthy application.

Please respond to the following questions:

- 1) It is unclear from review of the application if the compounding pharmacy will compound, fill individual Dr. written prescriptions, ship, and bill the individual patient, or if there will be local Tennessee pharmacies that fill the prescriptions from supplied compounded formulas. In one area of the application it is stated "2 or 3 pharmacies and a compounding pharmacy". Will each share a role or will the La. Pharmacy be doing all? Please clarify.
- 2) Could you please explain your reasoning for selecting Tennessee, Utah, and Florida for Home Health services instead of States contiguous to New Jersey?
- 3) It is understood that Mr. Purtrino is an experienced and licensed pharmacist, as well as having experience in home infusion and intrathecal pump infusion. However, to date IPM has had no historical track record of these services. Please explain how, as a newly formed entity, you intend to demonstrate you can provide a safe and effective service? How will individual Doctors and third party payors evaluate and potentially select your company to provide these services to their patients and insured?
- 4) What if any, relationship (professional or financial) involvement does the applicant have with Medtronics and Flowonix?

Thank you in advance for your prompt response.

Joe F. Culp, Health Planner III
Tennessee Department of Health
Division of Policy, Planning, and Assessment
Andrew Johnson Tower
710 James Robertson Parkway
Nashville, Tennessee 37243
615-741-0244
Fax 615-253-1688

Please see answers to the second set of questions below.

From: Joe F. Culp [mailto:Joe.F.Culp@tn.gov]
Sent: Friday, October 17, 2014 9:42 AM

To: Melissa Hess

Cc: Trent Sansing; Jeff Ockerman

**Subject:** IPM CON Application questions

Ms. Hess: Thank you for your timely responses to my previous requests. I have several more now and perhaps more later and I delve through this lengthy application.

Please respond to the following questions:

1) It is unclear from review of the application if the compounding pharmacy will compound, fill individual Dr. written prescriptions, ship, and bill the individual patient, or if there will be local Tennessee pharmacies that fill the prescriptions from supplied compounded formulas. In one area of the application it is stated "2 or 3 pharmacies and a compounding pharmacy". Will each share a role or will the La. Pharmacy be doing all? Please clarify. IPM will utilize two or more compounding pharmacies that fill individual Dr. written prescriptions, ship, and bill the individual pts. insurance. The selected compounding pharmacies that IPM intends to contract with are which are fully licensed and accredited to provide intrathecal medications are Basic Home Infusion and ICS. IPM does intend to increase the compounding pharmacy network if needed for patient

- coverage if necessary, but at that point the selected compounding pharmacy and or pharmacies will be selected based on quality, accreditation and experience in intrathecal compounding.
- 2) Could you please explain your reasoning for selecting Tennessee, Utah, and Florida for Home Health services instead of States contiguous to New Jersey? Upon developing IPM's strategic business plan, there are multiple states such as Pennsylvania, NJ, Ohio, and numerous others, a Home Health Agency License is not required, in fact IPM is exempt from licensure due to the singular therapy that IPM proposes to deliver. I hope that this assists you in clarifying the strategic approach taken by IPM. The states selected are only the beginning of the projected business plan for IPM. Eventually IPM intends to extend its' network to multiple states, but this will take a significant amount of time. IPM's approach is to move strategically across the country and ascertain all required licensure for each applicable state in place prior to initiation of services.
- 3) It is understood that Mr. Purtrino is an experienced and licensed pharmacist, as well as having experience in home infusion and intrathecal pump infusion. However, to date IPM has had no historical track record of these services. Please explain how, as a newly formed entity, you intend to demonstrate you can provide a safe and effective service? How will individual Doctors and third party payors evaluate and potentially select your company to provide these services to their patients and insured? Although IPM is a new company, the time proven model that Roy Putrino has successfully utilized for over twenty years will be simulated. This model is effective, efficient, and focuses on quality. IPM has every confidence that the care delivered will be centered on exceptional care, clinical strength and overall patient benefit. MD's and insurance payors will be targeted by IPM professionals once IPM is able to do intrathecal home management in the state of Tennessee, this will focus and highlight the effective model and the overall quality of care that IPM will provide to the individual pts. in the homecare setting.
- 4) What relationship (professional or financial) involvement does the applicant have with Medtronics and Flowonix? The only relationship that exists between IPM, Medtronic, and Flowonix is a professional one that focuses on quality of care. No formal agreement of participation or preferred company has or will be made. Also no financial agreement has or will be made with either of the mentioned manufacturers.

Note to Agency Members: The applicant provided surveys and plans of correction, sanctions, monetary penalties, or judgments against said companies to Health Department staff. These are located in Attachment 2 of this report along with other monetary penalties, or judgments found by Department staff.

It should also be noted by Agency members that Intrathecal Compounding Specialists, reported by the applicant to be the other compounding pharmacy in addition to Basic Home Infusion, has had sanctions, judgments, and monetary penalties against them as well. Copies of these are also provided in Attachment 2.

#### **TENNCARE/MEDICARE ACCESS:**

IPM will not participate in the TennCare and Medicare programs. This service is not covered by Medicare.

The applicant estimates year one gross commercial insurance revenues of \$137,758.50 or 99% of total gross revenues and self-pay revenues of \$1,391.50 or 1% of total gross revenues

#### **ECONOMIC FACTORS/FINANCIAL FEASIBILITY:**

The Department of Health, Division of Policy, Planning, and `has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

**Project Costs Chart:** The Project Costs Chart is located on page 32 of the application.

The total project cost is \$13,038.

**Historical Data Chart:** There is no Historical Data Chart as this is a new provider in Tennessee.

**Projected Data Chart:** The Projected Data Chart is located on 35 of the application. The applicant projects 120 and 240 patients in years one and two with a net operating income of \$134,962 and \$369,562 each year, respectively.

The applicant's proposed gross charge per patient is \$100 and proposed gross charge per visit is \$200.

Due to the nature and specific type of therapy IPM provides, and the fact that no other home health agency provides this service currently, the applicant sees no other alternative to this project.

#### CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

IPM provided a list of all Home Health Agencies in Tennessee in Attachment 1. It appears the applicant has no formal agreements, contacts, or relationships with anyone.

According to the applicant, intrathecal pump management will contribute to the orderly development of healthcare by allowing individuals access to higher access to a higher quality of care while simultaneously working with the patient to optimize therapy outcomes and increasing quality of life outcomes. IPM believes that allowing an intrathecal pump management company into Tennessee has the potential to greatly reduce overall health care costs.

The applicant's staffing will include 2.0 FTE registered nurses initially. When the applicant reaches their goal of 120 patients, they envision needing a total of 3.0 FTE registered nurses. Each FTE will be responsible for an area of 180 miles radius from the FTE's home.

IPM will not participate in the training or education of students in medicine, social work, nursing, etc.

If the CON is approved, the applicant will seek licensure from the Tennessee Department of Health, Board for Licensing Healthcare Facilities. According to the applicant, they have preliminary accreditation for all services under Comprehensive Accreditation Manual for Home Care in Florida for six months, beginning July 19, 2014.

#### SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

#### **HOME HEALTH SERVICES**

- 1. The need for home health agencies/services shall be determined on a county by county basis.
  - Please see Attachment 1.
- 2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.
  - The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
  - There is no need for Home Health Services in Tennessee. The Department of Health, Division of Policy, Planning, and Assessment, calculated the need for Home Health Services to be a **surplus of 81,654**.

3. Using recognized population sources, projections for four years into the future will be used.

See Attachment 1.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

There is no need for Home Health Services in Tennessee. The Department of Health, Division of Policy, Planning, and Assessment, calculated the need for Home Health Services to be a **surplus of 81,654**.

- 5. Documentation from referral sources:
  - a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.
    - In Supplemental 4, the applicant supplies a letter from William R. Schooley, MD of Nashville, Tennessee, and a letter from Comprehensive Pain Specialists with an illegible signature also from Nashville. It does not appear that the applicant adequately meets this criterion.
  - b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.
    - The applicant states the referring physicians would be those who refer their patients to IPM to do all pump refills, titrations, MRI checks, and changes in status in the homecare setting.
  - c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.
    - The applicant provides two form letters from potential patients in Supplemental 1. One is from Gainesboro, Tennessee and the other is from Lebanon, Tennessee. It does not appear the applicant adequately meets this criterion.
  - The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.
     N/A
- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
  - a. The average cost per visit by service category shall be listed.
  - b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant's proposed gross charge per patient is \$100 and proposed gross charge per visit is \$200.

### ATTACHMENT 1

### Tennessee Population Estimates 2014 and 2018 *

		4.11								
	Pop	ulation Estin	nate 2014	7	Popul	ation Entire				
Tennessee	lotal	18+	0/101	1	Population Estimate 2018 Total 18+ %18+		1 1	% Increase		
Anderson	1000,0	98 5,083,70	The latest and the la		6,833,50	5,307,35		linear land	18+	Total
Bedford	76,5	The second secon			77,85	62,95			4.4%	
Benton	47,3		THE RESERVE TO SERVE THE PARTY OF THE PARTY		50,566		0 74.8%		3.1%	
Bledsoe	16,2				16,104				7.7%	
Blount	12,64			繼	12,599				-0.6%	-0.9%
Bradley	128,36			150	135,171	107,275			1.2%	-0.3%
Campbell	103,30			经	107,481	84,506			6,1%	5.3%
Cannon	41,47		78.8%		42,566	33,757			5.4%	4.0%
	14,12		79.1%	21	14,540	11,537	A Company of the Comp		3.3%	2.6%
Carroll Carter	28,11		78.6%		27,831				3.3%	2.9%
	57,28		80.4%		57,680	21,921		0000	-0.8%	-1.0%
Cheatham	39,85		77.8%		40,765	46,531	100		1.0%	0.7%
Chester	17,47	2 13,624		3	17,999	33,601	TATIONING TO SAME		8.4%	2.3%
Claiborne	32,60	4 26,001				14,095	100000000000000000000000000000000000000		3.5%	3.0%
Clay	7,70	2 6,141			33,280	26,485			1.9%	2.1%
Cocke	36,76	2 28,237	76.8%		7,673	6,113			-0.5%	-0.4%
Coffee	54,27		77.3%		38,615	28,570			1.2%	5.0%
Crockett	14,590		75.9%		56,841	44,096	77.6%		5.1%	4.7%
Cumberland	57,81		80.9%		14,683	11,292	76.9%		1.9%	
Davidson	656,385	505,898			60,292	48,212	80.0%		3.1%	0.6%
Decatur	11,822		77.1%		682,330	518,945	76.1%		2.6%	4.3%
DeKalb	18,952	14,773	79.0%		12,080	9,515	78.8%		1.8%	4.0%
Dickson	50,860		77.9%	. Eli	19,125	15,003	78.4%		1.6%	2.2%
Dyer	38,218		77.4%	ė (e)	51,964	42,393	81.6%		7.7%	0.9%
Fayette	40,930		76.4%		38,427	29,652	77.2%		1.6%	2.2%
Fentress	18,404		79.0%		44,888	35,843	79.8%		10.8%	0.5%
ranklin	41,230		78.1%		18,987	14,947	78.7%		4.0%	9.7%
Gibson	51,102		79.0%		42,122	33,327	79.1%		2.3%	3.2%
Giles	29,315		76.0%		52,163	39,993	76.7%		3.0%	2.2%
Grainger	23,111	18,110	78.5%		29,285	23,099	78.9%		0.3%	2.1%
Greene	70,187	55,882	78.4%	1	23,675	18,371	77.6%		1.4%	-0.1%
Frundy	13,355		79.6%		71,594	57,176	79.9%	-	2.3%	2.4%
lamblen	64,108	10,379	77.7%		13,293	10,456	78.7%			2.0%
lamilton	347,451	49,432	77.1%		65,570	51,054	77.9%		0.7%	-0.5%
lancock		273,939	78.8%		353,577	278,518	78.8%		3.3%	2.3%
ardeman	6,652	5,288	79.5%		6,640	5,280	79.5%	-	1.7%	1.8%
ardin	26,359	21,111	80.1%	W.	26,067	21,011	80.6%	<b>I</b>	-0.2%	-0.2%
awkins	26,012	20,672	79.5%	8	26,244	20,925	79.7%	-	-0.5%	-1.1%
aywood	57,509	46,208	80.3%		58,164	48,679	83.7%	-	1.2%	0.9%
enderson	18,117	13,817	76.3%		18,009	13,831			5.3%	1.1%
enry	28,186	21,713	77.0%		28,631	22,392	76.8%	1	0.1%	-0.6%
ickman	32,697	25,566	78.2%		32,956	25,785	78.2%		3.1%	1.6%
ouston	24,422	19,358	79.3%		24,698	19,882	78.2%		0.9%	0.8%
	8,388	6,500	77.5%		8,447	6,621	80.5%		2.7%	1.1%
imphreys	18,498	14,465	78.2%		18,561	14,610	78.4%		1.9%	0.7%
ckson fferson	11,368	9,207	81.0%	1	11,495		78.7%		1.0%	0.3%
hnson	53,729	42,467	79.0%		56,872	9,348	81.3%		1.5%	1.1%
ox	18,094	14,891	82.3%	$\vdash$	18,127	45,403	79.8%		6.9%	5.8%
(e	453,629	357,424	78.8%		A STATE OF THE PARTY OF THE PAR	14,992	82.7%		0.7%	0.2%
iderdale	9,732	8,510	87.4%		9,468	76,924	79.3%	372 7	5.5%	4.8%
	27,341	20,945	76.6%	-	A CONTRACTOR OF THE PARTY OF TH	8,327	87.9%		-2.2%	-2.7%
wrence	42,329	32,110	75.9%	_	-	21,090	77.8%		0.7%	-0.8%
			1000000	-	72,007	32,497	76.7%		1.2%	0.1%

### Tennessee Population Estimates 2014 and 2018 *

	Population Estimate 2014 Total 18+ %18+				Population Estimate 2018			I	% Increase	
Lewis		18+	%18+		Total	18+	%18+	ı	18+	Total
Lincoln	12,112 34,281	9,378	77.4%		12,224	9,584	78.4%		2.2%	0.99
Loudon	50,926	26,860	78.4%		35,697	27,879	78.1%		3.8%	4.19
McMinn	53,233	41,531	81.6%		53,192	44,218	83.1%		6.5%	4.49
McNairy		41,669	78.3%		54,203	42,552	78.5%		2.1%	1.89
Macon	26,582	20,660	77.7%		27,299	21,349	78.2%		3.3%	2.79
Madison	23,188	17,690	76,3%		24,121	18,797	77.9%		6.3%	4.0%
Marion	99,555 28,556	75,976	76.3%		101,001	77,086	76.3%		1.5%	1.5%
Marshall		22,650	79.3%		28,992	23,238	80.2%		2.6%	1.5%
Maury	31,286 82,280	23,965	76.6%		32,015	24,856	77.6%		3.7%	2.3%
Meigs		62,826	76.4%	8	83,256	64,215	77.1%		2.2%	1.2%
Monroe	12,205	9,855	80.7%		12,643	10,404	82.3%		5.6%	3,6%
Montgomery	46,092	36,256	78.7%		48,088	38,574	80.2%		6.4%	4.3%
Moore	187,649	132,604	70.7%	30	200,561	139,824	69.7%		5.4%	6.9%
Morgan	6,350	5,061	79.7%	慧	6,401	5,152	80.5%		1.8%	0.8%
Obion	21,848	17,554	80.3%		22,004	17,909	81.4%		2.0%	0.7%
Overton	31,453	24,619	78.3%		31,222	24,690	79.1%		0.3%	-0.7%
Perry	22,489	17,463	77.7%		22,967	17,938	78.1%		2.7%	2.1%
Pickett	8,014	6,275	78.3%		8,096	6,416	79.2%		2.2%	1.0%
Polk	5,019	4,078	81.3%	鰀	4,943	4,056	82.1%		-0.5%	-1.5%
Putnam	16,604	13,155	79.2%	麗.	16,588	13,363	80.6%		1.6%	-0.1%
Rhea	77,024	59,787	77.6%		82,623	62,854	76.1%		5.1%	7.3%
Roane	33,392	26,086	78.1%		34,790	27,536	79.1%		5.6%	4.2%
Robertson	54,006 70,391	43,452	80.5%		54,457	44,459	81.6%	<b>20</b>	2.3%	0.8%
Rutherford	293,582	53,384	75.8%		74,371	59,728	80.3%		11.9%	5.7%
Scott	21,944	219,365	74.7%		329,446	247,954	75.3%		13.0%	12.2%
Sequatchie	15,019	16,677	76.0%		21,969	16,847	76.7%		1.0%	0.1%
Sevier	94,833	11,946	79.5%		16,004	13,075	81.7%		9.5%	6.6%
Shelby	943,812	74,728	78.8%	<b>8</b>	100,362	79,511	79.2%		6.4%	5.8%
Smith	19,618	704,633	74.7%		954,012	718,611	75.3%		2.0%	1.1%
Stewart	13,549	15,119	77.1%		20,281	15,872	78.3%		5.0%	3.4%
Sullivan	158,975	10,572	78.0%		13,941	10,977	78.7%		3.8%	2.9%
Sumner	172,262	129,556	81.5%		161,136	136,255	84.6%		5.2%	1.4%
Tipton	63,865	131,011	76.1%		183,406	141,247	77.0%		7.8%	6.5%
Frousdale	8,167	48,247	75.5%		67,545	52,390	77.6%		8.6%	5.8%
Unicoi	18,376	6,321	77.4%	<u></u>	8,582	6,701	78.1%		6.0%	5.1%
Jnion		14,767	80.4%		18,511	15,039	81.2%	8	1.8%	0.7%
/anBuren	19,301	14,996	77.7%		19,605	15,503	79.1%		3.4%	1.6%
Varren	5,450	4,401	80.8%		5,474	4,436	81.0%		0.8%	0.4%
Vashington	40,489	30,909	76.3%		41,155	31,728	77.1%		2.6%	1.6%
Vasnington Vayne	130,586	104,372	79.9%	8	138,370	109,665	79.3%		5.1%	6.0%
Vayne Veakley	16,854	13,742	81.5%		16,724	13,753	82.2%		0.1%	-0.8%
Vhite	38,522	31,009	80.5%		39,491	31,234	79.1%	200	0.7%	2.5%
Villiamson	26,871	20,929	77.9%	M _	27,974	21,777	77.8%		4.1%	4.1%
Vilson	202,923	147,874	72.9%	5	223,333	167,251	74.9%		13.1%	10.1%
VIISOIT	124,073	94,491	76.2%		133,357	102,945	77.2%		8.9%	7.5%

^{* 2013} Tennessee Population Series.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

### ATTACHMENT 2

### South Carolina Board of Pharmacy MINUTES

Board Meeting 9:00 a.m., November 19 2008 SC Pharmacy Association 1350 Browning Road Columbia, South Carolina

Wednesday, November 19, 2008

Meeting Called to Order

Davis Hook, R.Ph., chairman, of West Columbia, called the regular meeting of the SC Board of Pharmacy to order at 9:00 a.m. Other Board members participating in the meeting included: Allen Toole, R.Ph., vice chairman, of Liberty; David Banks, R.Ph., of Simpsonville; Bobby Bradham, R.Ph., of Charleston; Dan Bushardt, R.Ph., of Lake City; Hugh Mobley, R.Ph., of Lancaster, Leo Richardson, Ph.D., of Columbia; and Dock Henry Rose, R.Ph., of Greer.

Staff members participating during the meeting included: Lee Ann Bundrick, R.Ph., Administrator; Marilyn Crouch, Program Assistant; Eddie Durant, R.Ph., Temporary Investigator; Joe Newton, R.Ph., Pharmacist Investigator; Tom Porter, R.Ph., Pharmacist Investigator; and Clelia Sanders, R.Ph., Pharmacist Investigator. LLR employees participating during the meeting included: Randy Bryant, Assistant Deputy Director; Sharon Dantzler, Deputy General Counsel, Office of General Counsel; Pat Hanks, Attorney, Office of General Counsel; and Bob Selman, LLR Legislative Liaison.

Members of the public attending the meeting included: Victor Arzabe, Mark Boesen, Stephanie Bryant, Carmelo Cinqueonce, Senator Ronnie Cromer, Jon Davidson, Joanne Epley, Kevin Floyd, Wilbur Harling, Ken Hipshfur, Toni Hurdle, Brandi Johnson, Megan Montgomery, Ken Monroe, Carolyn Moore, Joe Mullinax, Christy Pettit, Thomas Phillips, Vimal Porag, Roy Putrino, Eric Ridings, Nasim Roosin, Frank Sheheen, Robert Spires, Rob Stone, and Rick Wilson.

Mr. Hook announced that this meeting was being held in accordance with Section 30-4-80 of the S. C. Freedom of Information Act by notice mailed to The State Newspaper, Associated Press, WIS-TV and all other requesting persons, organizations, or news media. In addition, notice was posted on the bulletin boards at the two main entrances of the Kingstree Building and the front entrance of the SC Pharmacy Association.

#### Invocation

Mr. Bushardt delivered the invocation.

#### Pledge of Allegiance

All present recited the Pledge of Allegiance.

### Chairman's Remarks - Davis Hook, R.Ph.

Mr. Hook thanked the SC Pharmacy Association for allowing the Board to meet at their facility and thanked staff for preparing for the meeting.

### Introduction of Board Members and all others attending

The Board members, staff and members of the public attending the meeting introduced themselves.

Mr. Hook informed Mr. Boesen the Board would take his testimony under advisement and would discuss the matter in executive session in order to seek legal advice.

E. Request Approval of Non-Resident Pharmacy – Basic Home Infusion, Roy Putrino

Roy Putrino appeared before the Board by conference call during the September 17, 2008 meeting regarding the permit application for Basic Home Infusion. The application included a cease and desist order and an attachment addressing violations and fines totaling \$7,650.00 from the New Jersey Board of Pharmacy. During that meeting Mr. Mobley questioned Mr. Putrino regarding compounding issues, the company's policies and procedures, and USP<797>. Also during that meeting the Board voted to deny the application until such time Mr. Putrino could document current compliance with the current USP<797> guidelines.

Roy Putrino appeared before the Board at this time and offered the following testimony.

Basic Home Infusion is a joint commission accredited specialty infusion pharmacy which provides only one therapy. The pharmacy was deficient in two areas according to the joint commission's guidelines: the pressure gauge and fingertip testing. The pressure gauge has now been purchased and installed. He presented information regarding the fingertip testing.

Basic Home Infusion runs tests independently with Western Slope on off label pain medications. The company does selective testing on drugs containing combinations on which the company is not familiar. The company is taking the lab test results to determine 90 % potency to establish the day time line to determine the beyond use date. All products are patient specific but shipped to a registered nurse. Everything is billed to the patient's insurance.

Mrs. Sanders stated she had reviewed the documentation Mr. Putrino had mailed to the Board. She noted the policies and procedures address several procedures she did not think the facility was doing and address several matters happening in hospitals.

Mr. Putrino stated he addressed other issues in the policies and procedures to establish a policy should the pharmacy address those issues. He is heavily involved with hospital since the therapies are not available in the hospital. All employees, including pharmacy technicians, are required to take continuing education training.

Mr. Hook informed Mr. Putrino the Board would take his testimony under advisement and would discuss the matter in executive session to seek legal advice.

F. SC DHEC MOA – Joanne Epley, R.Ph.

Joanne Epley, of DHEC, appeared before the Board at this time to discuss the Memorandum of Agreement regarding a declared disaster by the Governor.

MOTION

Mr. Rose made a motion the Board approve the MOA. Mr. Banks seconded the motion, which carried unanimously.

G. Pharmacists Dispensing on Public Health Orders - Joanne Epley, R.Ph.

Joanne Epley, of DHEC, appeared before the Board at this time to discuss pharmacists dispensing on public health orders. The US Department of Health and Human Services, part of



KIM GUADAGNO Lt. Governor

### New Jersey Office of the Attorney General

Division of Consumer Affairs Board of Pharmacy 124 Halsey Street, 6th Floor, Newark, NJ 07102



JEFFREY S. CHIES

Acting Director

Malling Address: P.O. Box 45013 Newark, NJ 07101 (973) 504-6450

### BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR MARCH 27, 2013

### I. CALL TO ORDER

The Open Meeting of the New Jersey Board Of Pharmacy was called to order by the Board President Edward McGinley in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on March 27, 2013, at 9:00a.m. All members were duly notified of the time, place and all pertinent materials were provided to members.

### II. SUNSHINE LAW ANNOUNCEMENT

President Edward McGinley, read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirements of Open Public Meetings Act N.J.S.A., Chapter 231, PL 1975, C.10:4-8

### III. ROLL CALL

Edward G. McGinley, R.Ph. Thomas Bender, R.Ph. Margherita Cardello, R.Ph. Marc Sturgill, R. Ph. Richard Palombo, R.Ph. Mahesh Shah, R.Ph. Stephen Lieberman, R.Ph. President Vice President Late Arrival 9:25 a.m.

### OTHERS IN ATTENDANCE

Anthony Rubinaccio Linda Brodie Matthew Wetzel Jodi Krugman Megan Cordoma

Executive Director Customer Service Rep. Government Rep. Deputy Attorney General Deputy Attorney General

### IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of February, \$16,725 was collected in fines and penalties. The following permit, licenses, and registrations were issued during the month of February:

New Jersey Board of Pharmacy Open Minutes March 27, 2013 page 3

3. Kenneth Grossett, R.Ph. - Request for modification of Consent Order

Mahesh Shah moved, seconded by Marc Sturgill, to modify his Consent Order by reducing urine screens from once a month to quarterly based on seven years in recovery and PAPNJ recommendation. Motion passed 6-0.

4. Alan Kay, R.Ph. - Request for modification of Consent Order

The Board reviewed all documentation received. Marc Sturgill moved, seconded by Margherita Cardello, that before the Board offers a decision Mr. Kay is to complete item number one of his Consent Order. Thomas Bender was recused due to his affiliation with Walgreens. Motion passed 6-0.

5. Randall Higgins, R.Ph. - Request for modification of Consent Order

Mr. Higgins is requesting a clarification of item number four on his Consent Order, to help him decide on a job offer. The Board reviewed all documentation received. Richard Palombo moved, seconded by Mahesh Shah, to put in place a letter of agreement between the Board and Roy Putrino, RPIC of Basic HomeInfusion. The letter is to include: reports on Mr. Higgins job performance sent quarterly; notification to the Board within twenty four hours if there is any type of problem concerning Mr. Higgins; and his evening work is to be reviewed every morning, by Mr. Putrino. Under separate correspondence the Board is requesting a clarification of Mr. Higgins daytime work duties verses his night duties and a list of narcotics that will be used in the compounding processes.

Motion passed 7-0.

 Camden County Health Services Center - Waiver for dispensing to discharged patients

Margherita Cardello moved, seconded by Thomas Bender, to deny waiver. Carden County Health Services Center is required to apply for a retail permit or utilize a different contract retail pharmacy. Motion passed 7-0.

 National Association of Boards of Pharmacy - Election of New Jersey voting delegate to NABP

Richard Palombo moved, seconded by Stephen Lieberman, to nominate Thomas Bender as delegate. Motion passed 7-0

Stephen Lieberman moved seconded by Mahesh Shah to nominate Richard Palombo as an alternate delegate. Motion passed 7-0.

 Bill Comment Request - S-2615, establishes prescription drug donation repository program

Stephen Lieberman moved, seconded by Richard Palombo, to opposed the bill in its current form, for public safety concerns (accepting medication returns from individual patients cannot assure that product integrity or stability has been maintained). All



KIM GUADAGNO Lt. Governor

### New Jersey Office of the Attorney General

Division of Consumer Affairs Board of Pharmacy 124 Halsey Street, 6th Floor, Newark, NJ 07102



THOMAS R. CALCAGNI Director

Mailing Address: P.O. Box 45013 Newark, NJ 07101 (973) 504-6450

### BOARD OF PHARMACY

**OPEN SESSION AGENDA** 

SOMERSET ROOM, 6th FLOOR

November 9, 2011

- I. CALL TO ORDER
- II. SUNSHINE LAW ANNOUNCEMENT
- III. ROLL CALL
- IV. UPDATE BY EXECUTIVE DIRECTOR
- V. OLD BUSINESS
  - 1) Finalization of Provisional Orders of Discipline
    - a) Nick R. Coleman, technician

### VI. NEW BUSINESS

- 1) Kan Solanki, PharmD requesting a waiver of NJAC 13:39-2.1(a)4
- 2) Bob Colonna Dept. of Superintendent Middlesex County Weights & Measures Regarding NJAC 13:39-5.8(a)5
- 3) Mark Pyatak, R.Ph. Request for modification of Consent Order
- 4) Neelan Chand, R.Ph. Request for modification of Consent Order
- 5) Kenneth W. Grossett II, R.Ph. Request for an unrestricted license

#### VII. MITIGATION/ HEARING REQUESTS

1) Jason Wood, R. Ph. - Walgreens Pharmacy

Mr. Hook informed Mr. Boesen the Board would take his testimony under advisement and would discuss the matter in executive session in order to seek legal advice.

 Request Approval of Non-Resident Pharmacy – Basic Home Infusion, Roy Putrino

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MOTION

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# STATE OF ILLINOIS ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION DIVISION OF PROFESSIONAL REGULATION

DEPARTMENT OF FINANCIAL A REGULATION, DIVISION OF PRO of the State of Illinois,	FESSIONAL REGULATION )	
of the state of Illinois,	Complainant,	
V.	)	No. 2012-04074
BASIC HOME INFUSION, INC.	į.	
License No. 054-016441	Respondent )	

### CONSENT ORDER

The Illinois Department of Financial and Professional Regulation, Division of Professional Regulation (hereinafter the "Department") by Scott A. Golden, its attorney, and BASIC HOME INFUSION, INC., Respondent, by and through its authorized representative, agree to the following:

### STIPULATIONS

BASIC HOME INFUSION, INC. is licensed as a pharmacy in the State of Illinois, holding License No. 054-016441. Said ficense is presently in active status. At all times material to the matter set forth in thi. Consent Order, the Department had jurismed an over the subject matter and parties to this Consent Order.

On or about February 10, 2004, Respondent was ordered to pay a penalty of Three Thousand Six Hundred Twenty-Five Dollars (\$3,625.00) following an inspection of its New Jersey pharmacy by the New Jersey State Board of Pharmacy. On or about March 3, 2004, Respondent successfully challenged a portion of the penalty and paid Two Thousand Five Hundred Twenty-Five Dollars (\$2,525.00) to the New Jersey State Board of Pharmacy. On or about January 26, 2006, Respondent was ordered to pay a penalty of Seven Thousand Six Hundred Fifty Dollars (\$7,650.00) and to provide a Letter of Correction following an inspection of its New Jersey pharmacy by the New Jersey State Board of Pharmacy. On or about May 10, 2006, Respondent successfully challenged a portion of the penalty and

was required to pay Five Thousand Six Hundred Fifty Dollars (\$5,650.00) to the New Jersey State Board of Pharmacy. On or about December 22, 2009, Respondent was ordered to pay a penalty in the amount of One Thousand Three Hundred Dollars (\$1,300.00) and provide a Letter of Correction following an inspection of its New Jersey pharmacy by the New Jersey State Board of Pharmacy. Respondent paid the full penalty. On or about October 12, 2011, Respondent was issued a warning by the New Jersey State Board of Pharmacy for having prescription labels that do not have the current address of the pharmacy. Respondent did not disclose said disciplines by the New Jersey State Board of Pharmacy to the Department until submitting a Change of Address Application.

The aforementioned conduct as set forth herein, if proven to be true, would constitute grounds for discipline of Respondent's license as a pharmacy in the State of Illinois on the authority of 225 ILCS 85/30(a)(8)(2011).

Respondent admit the Department's allegations.

Illinois State Board of Pharmacy Member Sud! The Man was consulted in this matter.

Respondent to even advised of the right to have the pending allegation reduced to written charges, the right to counsel, the right to a hearing, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waive each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation. Respondent acknowledge that it has entered into this Consent Order freely and of its own will without threat or coercion by the Department or any person. Respondent acknowledge that the Department attorney may be requested to communicate with the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation in furtherance of the approval of this Consent Order.

Respondent and the Department have agreed in order to resolve this matter that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of disciplinary measures which are fair and equitable in these circumstances and which are consistent with the best interest of the people of the State of Illinois.

### CONDITIONS

WHEREFORE, the Department, through Scott A. Golden, its attorney, and BASIC HOME INFUSION, INC., Respondent, by and through its authorized representative, agree:

- A. The license of BASIC HOME INFUSION, INC., License No. 054-016441, to practice as a pharmacy in the State of Illinois is hereby REPRIMANDED.
- B. This Consent Order shall become effective immediately upon signing and approval by the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation.

### DIVISION OF PROFESSIONAL REGULATION of the State of Illinois

	of the State of Illinois
7/10/12 DATE	Scott A. Golden Attorney for the Department
6.8.2012 DATE	110
	by its authorized representative, Respondent
7-10-12	- 1.
DATE	Sudhir C. Manek, R.Ph. Member, Illinois State Board of Pharmacy
THIS CONSENT ORDE	R IS APPROVED IN FULL:
DATED THIS 140	DAY OF Que just 2012.
	PROFESSIONAL REGULATION
	OF THE STATE OF ILLINOIS BRENT E. ADAMS, SECRETARY DIVISION OF PROPERTY

JAY STEWART

PĮVISION OF PROFESSIONAL REGULATION

Ref: Case No. 201104074 License Nos. 054016441

### STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION of the State of Illinois, Complainant	)	
v.	)	201204074
BASIC HOME INFUSION, INC. Respondent	)	

NOTICE

TO: BASIC HOME INFUSION, INC. ROY C. PUTRINO 1401 VALLEY ROAD, 4TH FLR. WAYNE, NJ 7470

PLEASE TAKE NOTICE that the Director of the Division of Professional Regulation did sign the attached Consent Order.

The Order of the Director of the Division of Professional Regulation will be implemented as of the date of the Order unless the Order states otherwise.

DIVISION OF PROFESSIONAL REGULATION of the State of Illinois

BY: Clerk for the Department

All inquiries should be Directed to: Chicago Office - 312-814-4504 Springfield Office - 217-785-0820

STATE OF ILLINOIS	, )	
COUNTY OF SANGAMON	)	38

UNDER PENALTY of perjury, as provided by law pursuant to Section 1-109 of the Illinois Code of Civil Procedure, the undersigned Certifies that I caused copies of the attached NOTICE AND CONSENT OR ORDER, to be deposited in the United States mail, by certified mail at 320 W. Washington, Springfield, Illinois 62786, before 5:00 p.m. with proper postage prepaid on the 14th day of August, 2012 to all parties at the addresses listed on the attached documents.

AFFIANT O

### BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-003982

### STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF BASIC HOME INFUSION, REGISTRATION NO. OSP 5793,

### RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Basic Home Infusion ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2011-003982 as follows:

- On February 4, 2009, Respondent Pharmacy became registered by the Board as a non-resident prescription drug outlet in the State of Colorado and was issued Registration No. OSP 5793 ("Colorado Registration").
- The Board has jurisdiction over Respondent Pharmacy, its Colorado Registration, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2010), otherwise known as the Pharmaceuticals and Pharmacists Act.
- Respondent Pharmacy's address of record with the Board and current location is 17-17 Broadway, Fair Lawn, NJ 07410.
- Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.
- 5. This is the second disciplinary action against Respondent Pharmacy for violations of Colorado's Electronic Prescription Drug Monitoring Program ("PDMP"). On November 1, 2010, Respondent Pharmacy entered into a Stipulation and Final Agency Order with the Board in which it agreed to a fine of \$5,000 with a 10% surcharge for PDMP violations pursuant to Board Policy 30-8. Respondent Pharmacy specifically acknowledged in the November 2010 Stipulation that future violations of PDMP requirements, including failure to submit a "zero" report in the event of no dispensing transactions in Colorado during the relevant reporting period as required by regulation, would lead to additional penalties pursuant to Board Policy 30-8, which in the case of a registrant with one or more prior disciplinary actions for

PDMP non-compliance includes a fine of ten thousand dollars plus a surcharge as required pursuant to §24-34-108, C.R.S., or voluntary relinquishment of the registration.

- 6. Respondent Pharmacy subsequently failed to submit the required data to the PDMP reporting dispensing transactions of controlled substances in the State of Colorado for the reporting period of April 1 through April 10, 2011, and did not submit a "zero" report indicating no dispensing transactions for said reporting period as required by Board rule.
- Respondent Pharmacy admits that the conduct described above constitutes a violation of §§12-22-125(1)(c) and 12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's Colorado Registration pursuant to Board Policy 30-8.

### DISPOSITION

### \$10,000.00 Fine with 10% Surcharge and Terms

- 8. Fine with Surcharge. Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S. Respondent Pharmacy shall pay a fine of Ten Thousand Dollars and No Cents (\$10,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total "amount of Eleven Thousand Dollars and No Cents (\$11,000.00). The total amount shall be payable to the State of Colorado and shall be remitted in monthly installments of \$1,100.00 beginning on September 1, 2011. The final installment of \$1,100.00 shall be remitted on June 1, 2012. Respondent Pharmacy shall write its registration number (OSP 5793) and the case number (2011-003982) on each installment it submits. Respondent Pharmacy shall immediately submit this signed Final Agency Order to the Board.
- 9. Compliance with PDMP. At all times Respondent Pharmacy is registered with the Colorado State Board of Pharmacy, it shall comply with the data submission requirements of the PDMP. Respondent Pharmacy understands and acknowledges that future violations of PDMP reporting requirements, including failure to submit a "zero" report in the event of no dispensing transactions in Colorado during the relevant reporting period, shall lead to additional penalties pursuant to Board Policy 30-8.
- 10. Advisements and Waivers. Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

a. To have a formal notice of hearing and charges served upon it;

To respond to said formal notice of charges;

c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and

d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

- 11. Acknowledgments. The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.
- 12. Other Requirements. Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent Pharmacy shall:
  - a. promptly pay all its own fees and costs associated with this Final Agency Order;
  - b. comply fully with this Final Agency Order; and
  - c. comply fully with the Pharmaceuticals and Pharmacists Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceutical and pharmacists in the State of Colorado.
- 13. Violations. Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
- 14. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or

unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

- 15. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
- 16. Effective Date. This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY	
Authorized Agent of Respondent Pharmacy Dated: 8/18/11	
Subscribed and sworn to before me in the County of TASSATE State of	÷
Home Infrusion. this A day of HUGUST, 2011 by	
My commission expires: 12/29/11 Malia a Motary Public	
NADIA SALMON Notary Public State of New Jersey	

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS LAW DAY OF ____ Suplembles 2011.

State Board of Pharmacy

Wendy Anderson

Program Director

### CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within STIPULATION AND FINAL AGENCY ORDER upon all parties herein by electronic mail and by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this 27 day of

August 2011, addressed as follows:

Basic Home Infusion Attn: Roy Putrino, RPH 17-17 Broadway Fair Lawn, NJ 07410 rputrino@basichi.com

> Sauri A. Oac Lauri A. Rose

### CERTIFICATE OF SERVICE

This is to certify that I have duly served the within STIPULATION AND FINAL AGENCY ORDER upon all parties herein by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this United day of Soptombox 2011, addressed as follows:

Basic Home Infusion Attn: Roy Putrino, RPH 17-17 Broadway Fair Lawn, NJ 07410

Agent of the Board



## Louisiana Board of Pharmacy 3388 Brentwood Drive

3388 Brentwood Drive Baton Rouge, Louisiana 70809-1700 www.pharmacy.la.gov



### **Minutes**

Regular Meeting

Wednesday, February 1, 2012 at 1:00 p.m.

Louisiana Board of Pharmacy 3388 Brentwood Drive Baton Rouge, Louisiana 70809-1700

Administrative Hearing

Thursday, February 2, 2012 at 8:30 a.m.

Louisiana Board of Pharmacy 3388 Brentwood Drive Baton Rouge, Louisiana 70809-1700 CVS Pharmacy No. 5360 (PHY.005774) Mr. Bond moved to approve the voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed the permit owner a fine of \$5,000 plus administrative and investigative costs.

Paul Stephen Sims (PST.010994) Mr. Bond moved to approve the voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand, and further, assessed a fine of \$500 plus administrative costs.

Southwest Medical Center (PHY.003089) Mr. Bond moved to approve the voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed the permit owner a fine of \$10,000 plus administrative and investigative costs.

Intrathecal Compounding Specialists, LLC (PHY.005856) Mr. Bond moved to approve the voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed the permit owner a fine of \$10,000 plus administrative and investigative costs.

Catherine Joette Pearson (CPT.007615) Mr. Bond moved to approve the voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the technician certificate for two years and stayed the execution thereof, and then placed the certificate on probation for two years, subject to certain terms enumerated in the consent agreement, and further, assessed administrative and investigative costs.

Finally, Mr. Bond expressed appreciation to the other members of the committee for their ongoing efforts.

Having completed the transferred agenda item, Mr. Aron returned to the posted agenda.

Wednesday, February 1, 2012

#### E. Impairment Committee

Mr. Aron called upon Mr. Rabb for the committee report. Mr. Rabb reported the committee met the previous day to consider eleven referrals from staff. He then presented the following files for Board action.

Sharron Renee Barnes Michael (PST.017155) Mr. Rabb moved to approve the voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board granted the request for reinstatement of the previously suspended license, converted the previous suspension from an indefinite term to a term of ten years and stayed the

3.1 0

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# The Law of Compounding Medications And Drugs

Human Medications, Human Drugs, Animal Medications, Animal Drugs, Pharmacy law, Pharmaceutical law, Compounding law, Sterile and Non Sterile Compounding 797 Compliance, Veterinary law, Veterinary Compounding Law; Health Care; Awareness of all Types of Compounding Issues, LISTED ON BEST SEARCHING 2012 & 2013; LISTED ON BEST BLOG Monday, July 15, 2012 \$10,000 fine Imposed Against Intrathecal Compounding Search, Specialists Purpose of Blog A blog dedicated to educating phormacists, Share The Louisana Board of Pharmacy assessed a fine of \$10,000 plus cost against doctors, veterinarians, and the general public Introthecal Compounding Specialists. The fine was for six counts, including accountability for the about the law in the United States relating to diversion of 220 pints of premothizing with codeine syrup and over 16,000 tablets of compounded medications for both humans and hydrocodone/scetaminophen 10/500 over a six month period of time poimals Source found here . Essential and Historical Documents Related to November 14, 2012 - Written testimony of Dr. Margaret A. Posted by Sue Richmondal 7/16/2012 05:24:00 PM Hamburg, M.D. before the House Committee on Energy and 3.1 Recommend this on Gracie Commerce, Subcommittee on Labels:Introlhecal Compounding Specallist Lousiana State Braid of Pharmacy Oversight and Investigations hearing "The Fungal Meningitis Outbreak: Could It Have Been No comments: Prevented? Post a Comment November 14, 2012 - Video of the testimoney of Dr. Mercaret A. Links to this post Hamburg, M.D. before the House Committee on Energy and Create a Link Commerce. November 15, 2012 - Written lestimony of Dr. Margaret A. Homburg, M.D., before the Newer Post Home Older Post Senate Committee on Health Education, Labor and Pensions Subscribe to Post Comments (Atom) Pharmacy Compounding: Implications ofthe 2012 Meningitis Outbreak* November 15, 2012 - Video of the Senate HELP Committee hearing. December 2012 - Transcript of FDA Meeting - "Framework for Pharmacy Compounding - State and Federal Roles* January 2013 - Comments. Submitted to FDA Docket regarding *Framework for Pharmacy Compounding - State and Federal Roles" April 16, 2013 - Whiten testimony of Dr. Margarel A. Hamburg before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations - "Continuing

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LOUISIANA COUPLE AWARDED NEARLY HALF-A-MILLION DOLLARS IN MEDICAL MALPRACTICE LAWSUIT Published under Medical Malpractice by Jennifer Keel

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A couple from Houma, Louisiana, was recently awarded more than \$400,000 in a lawsuit that claimed an overdose of a medicine led to the husband's severe sickness.

According to the Lafourche Daily Comet, the suit was filed in Terrebonne Courthouse, and claimed that Kirk Harvey showed symptoms similar to those of a stroke after he was given more than 20 times the allowed dosage of the medication clonidine.

Clonidine is used to treat high blood pressure, and works by lowering an individual's heart rate and relaxing the body's blood vessels to allow for increased blood flow. In the event of an overdose, the medication has been linked to slowing of the heart, slurred speech, confusion and weakness, according to the National Library of Medicine.

The lawsuit states Harvey was prescribed the medication by his doctor, which was then filled by the Lafayette-based company Intrathecal Compounding Specialists. The next day, Harvey returned to the doctor with feelings of "very light-headedness, dizziness and extreme fatigue," according to Harvey's medical malpractice lawyer.

In the trial, Judge David Arceneaux declared that Intrathecal Compounding was negligent, and awarded Harvey the sum, while his wife was given another \$10,000 for suffering incurred from her husband's illness.



#### Jennifer Keel

Jennifer has devoted her career to helping people who have been catastrophically injured by medical errors. She handles cases involving birth trauma, kernicterus, cerebral palsy and. other brain injuries, spinal cord injuries, as well as many other types of medical error resulting in catastrophic injury or death. Jennifer is also on the Adjunct Faculty at the University of Denver's Sturm College of Law, where she teaches law students about Medical Malpractice Law and Litigation.





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### Louisiana Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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### Board Member Appointments (12-04-405)

Louisiana Board of Pharmacy member appointments are made in accordance with La. R.S. 37:1175, which provides that whenever a vacancy occurs among the members representing one of the eight districts, the pharmacists who are bona fide residents of the district in which the vacancy occurs shall nominate, from among their number, a representative to the Board. Whenever the vacancy will occur by reason of an expiring term, the nominations shall be made by mail at least 60 days in advance of the expiration date of the term.

The Board's secretary is responsible for mailing a ballot, by United States First Class Mail, to each pharmacist holding an active license and residing in the district in which the vacancy will occur, at the last known address as indicated in the Board's records. The ballot, or another enclosed communication, will state the date, time, and place for counting ballots. At a gathering open to the public, the secretary and one or more persons designated by him or her will open and count the ballots. The secretary will then certify to the governor the names of the three nominees in each district receiving the highest number of votes. For each district in which the vacancy will occur, the governor may appoint one of those three nominees to the Board.

The terms of six current Board members will expire on September 15, 2012. The ballots with the necessary information will be mailed to pharmacists in the respective districts on or about June 1, 2012. The ballots will be opened and counted on July 10-11, 2012; information about the exact time and place will be included with the ballot.

Board member terms that will expire on September 15, 2012, and their districts, are as follows:

- Joseph L. Adams, Mandeville, LA (District 1, composed of the parishes of Jefferson and St Tammany).
- Blake P. Pitre, Houma, LA (District 3, composed of the parishes of Ascension, Assumption, Iberia, Iberville, Lafourche, St Charles, St James, St John the Baptist, St Martin, St Mary, Terrebonne, and West Baton Rouge).

- Lois R. Anderson, Shreveport, LA (District 4, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster).
- T. Morris Rabb, Monroe, LA (District 5, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll, and Winn).
- Chris B. Melancon, Carencro, LA (District 7, composed of the parishes of Acadia, Calcasieu, Cameron, Jefferson Davis, Lafayette, and Vermilion).
- Brian A. Bond, Jena, LA (District 8, composed of the parishes of Allen, Avoyelles, Beauregard, Catahoula, Concordia, Evangeline, Grant, LaSalle, Pointe Coupee, Rapides, St Landry, and Vernon).

Should any pharmacist need a list of pharmacists in his or her own district for purposes related to this nomination election, the Board office will supply one complimentary list upon written request by the pharmacist.

### New Continuing Education Procedures for Pharmacists and Technicians (12-04-406)

Have you had enough of managing all of those paper statements of credit documenting your continuing pharmacy education (CPE) activities? Good news—the end of the "paper chase" is near.

CPE Monitor™ is a collaborative service from the National Association of Boards of Pharmacy® (NABP®), the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers. The service will allow pharmacists and technicians to track their ACPE-accredited CPE activities electronically through the use of an e-Profile maintained by NABP. How does it work? When you register for an ACPE-accredited CPE activity, the provider will request your NABP e-Profile ID number, along with the month and day of your birth (MMDD). Following the CPE activity, the provider will electronically transmit the participation data to ACPE. Following verification of the data, ACPE will electronically transmit the CPE data to NABP.

### Continued from page 5

McGee's Pharmacy (PHY.004706): Permit revoked; for 14 counts, including improper closure of pharmacy and failure to transfer prescription records to another pharmacy.

Robert Mark McGee (PST.015107): Assessed a fine of \$1,000 plus costs, and further, a lifetime prohibition on the acceptance of an appointment as the pharmacist-in-charge of any pharmacy permitted by the Board; for 16 counts, including as owner and pharmacist-in-charge of McGee's pharmacy, the improper permanent closure of the pharmacy and failure to transfer prescription records to another pharmacy.

CVS Pharmacy No. 5360 (PHY.005774): Assessed a fine of \$5,000 plus costs; for six counts, including allowing a pharmacy technician with an expired certificate to continue to work in the prescription department.

Southwest Medical Center (PHY.003089): Assessed a fine of \$10,000 plus costs; for six counts, including accountability for the diversion of 398 pints of promethazine with codeine syrup over a two-year period.

Intrathecal Compounding Specialists (PHY.005856): Assessed a fine of \$10,000 plus costs; for six counts, including accountability for the diversion of 220 pints of promethazine with codeine syrup and over 16,000 tablets of hydrocodone/ acetaminophen 10/500 over a six-month period of time.

Catherine Joette Pearson (CPT.007615): Suspended certificate for two years and stayed the execution thereof, and then placed the certificate on probation for two years, effective January 1, 2012, subject to certain terms enumerated in the consent agreement; for seven counts, including forgery of prescriptions for phentermine and the subsequent processing thereof.

Mary Rush Schultz (PTC.017371): Revoked registration, with permanent prohibition on any future application for reinstatement; for four counts, including the diversion of controlled substances from her employer pharmacy.

Paul Thomas DelFavero (CPT.010194): Revoked certificate, with permanent prohibition on any future application for reinstatement; for five counts, including the diversion of controlled substances from his employer pharmacy.

Cathy Lynn Mitchell (CPT.001195): Revoked certificate, with permanent prohibition on any future application for reinstatement; for five counts, including the diversion of controlled substances from her employer pharmacy.

Laura Jean Fairbanks (CDS.029124-MD): Accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective January 11, 2012.

At the same meeting in February, the Board also issued letters of reprimand to two pharmacies and two pharmacists; and further, granted a request from one pharmacist to modify previously imposed probationary terms.

### Calendar Notes (12-04-410)

The next Board meeting and administrative hearing will be May 2-3, 2012, at the Board office. The office will be closed April 6, in observance of Good Friday.

### Special Note (12-04-411)

The Louisiana Board of Pharmacy Newsletter is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. These Newsletters will be used in administrative hearings as proof of notification. Please read them carefully. The Board encourages you to keep them in the back of the Louisiana Pharmacy Law Book for future reference.

Page 6 - April 2012

The Louisiana Board of Pharmacy News is published by the Louisiana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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# SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION BEFORE THE SOUTH CAROLINA BOARD OF PHARMACY

v	200	_00		
ln	the	M	atter	of

BASIC HOME INFUSION, INC.

ORDER

Applicant.

This matter is before the Board pursuant to the application, dated June 30, 2008, of BASIC HOME INFUSION, INC. (Applicant) for a permit to operate as a non-resident pharmacy in this State. In that application Applicant disclosed discipline by the State of New Jersey resulting from an inspection in December 2005. Applicant appeared without counsel before the board at its regular meeting on September 17, 2008.

Roy C. Putrino, RPh., and pharmacist in charge offered testimony that Applicant has corrected all deficiencies identified in 2005 and that the pharmacy is in good standing in New Jersey. He testified that he was familiar with the most recent edition of USP 797 but that the pharmacy was not yet in compliance. Further questioning revealed that pharmacy practices were not comparable to USP 797.

Initially, it should be recognized that in considering any application for licensure or permit, the burden is upon the Applicant to demonstrate to the satisfaction of this Board that it is qualified for permit for which it has applied and that it can practice the profession of pharmacy without danger to the public health. Applicant compounds products for intrathecal use and the Board notes that these products pose significant risks and require the highest degree of care in maintaining sterile conditions.

The South Carolina Board, by publication of its policies #132 and 137, has notified its licensees that if a pharmacy is compounding sterile products, the pharmacy shall be in compliance with the South Carolina Pharmacy Practice Act and review USP guidelines regarding the compounding of sterile products and keep abreast of any new changes. In the absence of confirming documentation that Applicant is abreast of the current USP 797 standards, this Board carinot make such a determination.

THEREFORE, IT IS ORDERED that this application be denied until such time that Applicant can document that its practices are in substantial compliance with the most current edition of USP 797.

AND IT IS SO ORDERED.

STATE BOARD OF PHARMACY

DAVIS C. HOOK, R. PH.

Chairman of the Board